THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 123772 **Seq:** 1 **Gender:** F
Reported: 05/01/1998 **Weight:** 64.00
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of 9kg	

Medicine Details:

CARDIPRIN 100 (Other drug) **Reason:** Chron isch heart dis no hyper
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 01/04/1997 **Stopped:**

TRIPHASIL (Other drug) **Reason:** Contraception
1.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 28/02/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 123805 **Seq:** 1
Reported: 05/01/1998
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 78.00
Age: 39Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 08/10/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Developed an increase of her bruising (already a problem) with large ecchymos- is on limbs at site of minor trauma.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 123898 **Seq:** 1 **Gender:** F
Reported: 12/01/1998 **Weight:** 65.00
Hospitalisation: **Age:** 34Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Hot sweats on one leg	
Hypoaesthesia		Numbness on lefthand side of her torso	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient is a recreational user of marijuana - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Report Detail

Case Number: 123926 **Seq:** 1 **Gender:** F
Reported: 14/01/1998 **Weight:** 69.00
Hospitalisation: **Age:** 61Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Sleep all night and much of the day	

Medicine Details:

PREMARIN (Other drug) **Reason:**
625.0 Microgram Daily
Batch: **Started:** **Stopped:**

VERACAPS SR (Other drug) **Reason:**
160.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/08/1996 **Stopped:** 30/08/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient doesn't tolerate valium (spaced out, visual disturbance).

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 123971 **Seq:** 1 **Gender:** F
Reported: 15/01/1998 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: 23/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Dry mouth Vaginal infection		Vaginal itch	Aropax ceased.

Medicine Details:

ZADINE (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:** CONTIN

ADALAT (Other drug) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 01/01/1990 **Stopped:** CONTIN

BETALOC (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** 01/01/1990 **Stopped:** CONTIN

ZYLOPRIM (Other drug) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 123971 **Seq:** 1 **Gender:** F
Reported: 15/01/1998 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: 23/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

LASIX (Other drug)		**Reason:**		
	40.0 Milligram	Daily		
Batch:	**Started:** 01/01/1995		**Stopped:**	CONTIN
ZANTAC (Other drug)		**Reason:**		
	300.0 Milligram	Daily		
Batch:	**Started:** 01/01/1996		**Stopped:**	CONTIN
AROPAX (Suspected)		**Reason:**	Depression	
	20.0 Milligram	Daily		
Batch:	**Started:** 17/12/1997		**Stopped:**	02/01/1998

Laboratory Investigations:

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124008 **Seq:** 1 **Gender:** F
Reported: 16/01/1998 **Weight:** 55.00
Hospitalisation: **Age:** 25Y
Onset Date: 24/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia Gait disturbance			Aropax discontinued

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124107 **Seq:** 1 **Gender:** F
Reported: 16/01/1998 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia		Loss off hair	Aropax reduced from 20mg daily to 10mg daily.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 124109 **Seq:** 1 **Gender:** F
Reported: 16/01/1998 **Weight:** 85.00
Hospitalisation: **Age:** 42Y
Onset Date: 31/03/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia Tremor		Left arm, leg and left side of face	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 18/03/1995 **Stopped:** 28/08/1996

ALPRAZOLAM (Suspected) **Reason:** Depression
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 18/03/1995 **Stopped:** 22/02/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Mri 08/12/97 reveals foci of subcortical t2 hypersensitivity present bifrontally and adjacent to the trigone of the left lateral ventricle query demyeliination query connective tissue disorder.

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124224 **Seq:** 1 **Gender:** M
Reported: 19/01/1998 **Weight:** 75.00
Hospitalisation: **Age:**
Onset Date: 31/12/1996 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough Dyspnoea Pulmonary fibrosis			Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 12/03/1994 **Stopped:** 28/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124225 **Seq:** 1 **Gender:** F
Reported: 19/01/1998 **Weight:**
Hospitalisation: **Age:** 67Y
Onset Date: 10/12/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			Aropax ceased. therapy changed to fluvoxamine.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/12/1997 **Stopped:** 13/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124259 **Seq:** 1 **Gender:** F
Reported: 20/01/1998 **Weight:** 60.00
Hospitalisation: **Age:** 38Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Extensive bruising over legs	Fbl/lft checked - normal

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 04/11/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124296 **Seq:** 1 **Gender:** F
Reported: 21/01/1998 **Weight:** 88.00
Hospitalisation: **Age:** 49Y
Onset Date: 27/12/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema Weight increased		Leg oedema Weight gain of about 1 1/2 stones.	Ceased dilantin and aropax.

Medicine Details:

KAPANOL (Other drug) **Reason:**
Capsule 100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

TEGRETOL (Other drug) **Reason:**
1.4 Gram Daily
Batch: **Started:** L TERM **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
Tablet 12.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 04/12/1997 **Stopped:** 09/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124296 **Seq:** 1
Reported: 21/01/1998
Hospitalisation:
Onset Date: 27/12/1997
Outcome: Not yet recovered

Gender: F
Weight: 88.00
Age: 49Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

DILANTIN (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** 17/12/1997 **Stopped:** 05/01/1998

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124305 **Seq:** 1 **Gender:** F
Reported: 21/01/1998 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: 17/01/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Tingling in arm.	
Asthenia		Weak all over.	
Eructation			
Nausea			

Medicine Details:

AMFAMOX (Other drug) **Reason:** Ulcer of stomach w/o ment perf
40.0 Milligram Daily
Batch: **Started:** 02/01/1998 **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: AUSTL51205 **Started:** 17/01/1998 **Stopped:** 17/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124341 **Seq:** 1
Reported: 22/01/1998
Hospitalisation:
Onset Date: 20/01/1998
Outcome: Recovered with sequelae

Gender: F
Weight: 57.00
Age: 42Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Anxiety Drug withdrawal syndrome Hypertension Syncope		Peripheral paraesthesia	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 16/05/1997 **Stopped:** 14/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on 40 mg aropax daily, dose was decreased, then one every second day. allergics codeine-nausea, septrin -swelling of tongue, rhondomycin-rash, maxolon-violently ill, provera-nausea.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124393 **Seq:** 1 **Gender:** F
Reported: 27/01/1998 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 14/05/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Confusional state Dizziness Drug withdrawal syndrome			Drug dose maintained on aropax 5mg, then cease again.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124394 **Seq:** 1 **Gender:** F
Reported: 27/01/1998 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: 31/12/1996 **DOB:** 24/03/1953
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysphonia		Hoarse inaudible voice.	Ceased aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/10/1996 **Stopped:** 28/06/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 124395 **Seq:** 1 **Gender:** M
Reported: 27/01/1998 **Weight:**
Hospitalisation: **Age:** 86Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension		Bp 195/100-190/80 from 130/70.	

Medicine Details:

LISINOPRIL (Other drug) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 05/01/1998 **Stopped:** 09/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was rechallenged on half dose of 10mg of aropax, same thing happened. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124453 **Seq:** 1 **Gender:** F
Reported: 28/01/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 23/12/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal aplasia		Babe born with absent left kidney, r side	Prophylactic trimethoprim until mcu, radionuclear scan, muct. cystourethrogram

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Ultrasound confirmed l kidney absence.

Additional Information:

1st babe of mother treated with paroxetine (b3 preg category) through pregnancy first 6 months. baby born 23/12/97. antenatal diagnosis of absent left kidney. large right kidney (probably compensatory hypertrophy). postnatally well with no physical abnormalities detected on examination.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124486 **Seq:** 1 **Gender:** F
Reported: 30/01/1998 **Weight:** 60.00
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 19/09/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Existing tremor was made worse.	Aropax ceased.

Medicine Details:

DIAZEPAM (Other drug)		**Reason:** Neuroses		
Tablet	30.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/05/1997		**Stopped:** 28/01/1998	
OXAZEPAM (Other drug)		**Reason:** Neuroses		
Tablet	90.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/02/1997		**Stopped:** 28/01/1998	
AROPAX (Suspected)		**Reason:** Phobic neurosis		
Tablet	40.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/07/1997		**Stopped:** 28/08/1997	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 124493 **Seq:** 1 **Gender:** M
Reported: 30/01/1998 **Weight:** 70.00
Hospitalisation: **Age:** 29Y
Onset Date: 31/08/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

VALIUM (Other drug) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

XANAX (Other drug) **Reason:**
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 08/08/1997 **Stopped:** 15/08/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124623 **Seq:** 1 **Gender:** M
Reported: 02/02/1998 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased		Sexual dysfunction	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124657 **Seq:** 1 **Gender:** F
Reported: 03/02/1998 **Weight:** 75.00
Hospitalisation: **Age:** 69Y
Onset Date: 12/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus			Withdrawal of paroxetine.

Medicine Details:

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124720 **Seq:** 1 **Gender:** F
Reported: 05/02/1998 **Weight:**
Hospitalisation: **Age:** 81
Onset Date: 15/01/1998 **DOB:** 26/07/1916
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon			Ceased paroxetine, fluid

Medicine Details:

ISOPTIN (Other drug) **Reason:** Essential benign hypertension
240.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/07/1997 **Stopped:** 29/01/1998

AMLODIPINE (Suspected) **Reason:** Essential benign hypertension
5.0 Milligram Daily
Batch: **Started:** **Stopped:** 26/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		26/12/1997	138	
	Sodium		15/01/1998	129	
	Sodium		18/01/1998	127	
	Sodium		28/01/1998	136	
	Urine Sodium		28/01/1998	27	
	Urine osmolality		18/01/1998	260	
	Urine osmolality		28/01/1998	653	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 124762 **Seq:** 1 **Gender:** M
Reported: 09/02/1998 **Weight:** 80.00
Hospitalisation: **Age:** 44Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Aropax ceased

Medicine Details:

DUCENE (Other drug) **Reason:** Anxiety neurosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/07/1997 **Stopped:** 12/12/1997

TRYPTANOL (Suspected) **Reason:** Specific disorders of sleep
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 01/05/1997 **Stopped:** 15/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				05/11/97 09/01/98 alt 149 68 ast 112 - ggt 734 430

Additional Information:

Past history: hepatitis a - many years. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124769 **Seq:** 1 **Gender:** F
Reported: 04/02/1998 **Weight:**
Hospitalisation: **Age:** 19
Onset Date: **DOB:** 09/12/1978
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/08/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124804 **Seq:** 1 **Gender:** F
Reported: 11/02/1998 **Weight:** 77.00
Hospitalisation: **Age:** 19Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Gait disturbance Muscle twitching			

Medicine Details:

AROPAX (Suspected) **Reason:** Debility&undue fatigue
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 21/01/1998 **Stopped:** 05/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124925 **Seq:** 1 **Gender:** M
Reported: 13/02/1998 **Weight:** 85.00
Hospitalisation: **Age:** 32Y
Onset Date: 29/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematuria Albuminuria Renal failure acute	 Severe	Blood in urine.	

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/07/1997 **Stopped:** 28/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Protein Urine creatinine		29/01/1998 29/01/1998	500MG 0.43MMOL/L	

Additional Information:

Date of recovery 09/02/98 the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124947 **Seq:** 1 **Gender:** M
Reported: 13/02/1998 **Weight:** 80.00
Hospitalisation: **Age:** 73Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Tongue unable to be still in mouth.	

Medicine Details:

ARICEPT (Suspected) **Reason:** Presenile dementia
Oral application 5.0 Milligram Daily Oral
Batch: **Started:** 02/12/1997 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 01/11/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 124959 **Seq:** 1 **Gender:** F
Reported: 13/02/1998 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 02/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 2D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 124960 **Seq:** 1 **Gender:** F
Reported: 13/02/1998 **Weight:** 57.00
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Severe	Antisocial/over-reactive/weeping/suicidal/vi	
Mania	Severe	Depressed	
Aggression	Severe	Noise tolerance was nil	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/02/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No adverse events were experienced following the start of treatment. patient was not admitted to hospital. symptoms resolved after a week or two of restarting aropax in late december 1997. the dose has been tapered gradually. method of tapering: one daily alternating with half daily for 1 week, then half daily for 1 week, then half on alternate days for 2 weeks, then stop. patient is currently well on aropax and feels that she benefitted overall from the medication but has doubts as to whether a physical dependence has resulted. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 124961 **Seq:** 1 **Gender:** F
Reported: 13/02/1998 **Weight:** 65.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 09/04/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Hyperhidrosis Somnolence Tremor		Increased tiredness Sweating palms	Aropax reduced.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 03/11/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is an adopted child. has had long history of anxiety and ocd in adulthood. symptoms experienced when patient on 40mg daily. symptoms resolved when the dose was decreased to 20mg/day.

Report Detail

Case Number: 124962 **Seq:** 1
Reported: 13/02/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 60.00
Age: 38Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Sleep extended.	
Visual disturbance		Slightly blurred vision.	
Aggression			
Dizziness			
Drug withdrawal syndrome	Severe		Aropax restarted.
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 2.0 Dose Unspecified Daily Oral

Batch: **Started:** 01/07/1993 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax restarted in january 1998. the symptoms resolved immediately. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125123 **Seq:** 1 **Gender:** U
Reported: 19/02/1998 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 05/06/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Muscle twitching			

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125124 **Seq:** 1 **Gender:** F
Reported: 19/02/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 02/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue		Exhaustion	
Chest pain			
Coma			Aropax ceased
Coordination abnormal			
Dehydration	Severe		
Headache			
Hyperglycaemia			
Hyperhidrosis			
Myalgia			
Vomiting			

Medicine Details:

NORVASC (Other drug) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/02/1998 **Stopped:** 02/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 125125 **Seq:** 1 **Gender:** F
Reported: 19/02/1998 **Weight:** 56.00
Hospitalisation: **Age:** 44Y
Onset Date: 30/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep walking			Aropax reduced to 10 mg

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 25/10/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 125139 **Seq:** 1 **Gender:** F
Reported: 19/02/1998 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oliguria		Inability to pass urine	
Thirst		Increased fluid intake	
Gravitational oedema			
Headache			
Increased appetite			

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 25/11/1997 **Stopped:** 09/02/1998

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 09/02/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125157 **Seq:** 1 **Gender:** F
Reported: 23/02/1998 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: 13/02/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism		Clenching of teeth.	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 10/02/1998 **Stopped:** 18/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125187 **Seq:** 1 **Gender:** F
Reported: 20/02/1998 **Weight:** 65.00
Hospitalisation: **Age:** 40Y
Onset Date: 06/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain		Burning pain	
Rash vesicular		Vesicular eruption	
Herpes zoster			
Rash			Zovirix

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 19/12/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125236 **Seq:** 1 **Gender:** F
Reported: 24/02/1998 **Weight:** 70.00
Hospitalisation: **Age:** 28
Onset Date: 07/02/1998 **DOB:** 23/05/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death		Miscarriage at 12 weeks.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/03/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 125260 **Seq:** 1 **Gender:** F
Reported: 25/02/1998 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 19/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			Warfarin and aropax ceased

Medicine Details:

COUMADIN (Interaction) **Reason:** Phleb&thrombophleb lowr extrem
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 04/11/1997

COUMADIN (Interaction) **Reason:** Phleb&thrombophleb lowr extrem
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** 05/11/1997 **Stopped:** 18/11/1997

AROPAX (Interaction) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 17/11/1997 **Stopped:** 18/11/1997

PANADOL (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International		18/11/1997	6.8	
	International		19/11/1997	4.9	
	International		20/11/1997	3.4	

Additional Information:

Patient had 3 inr tests after warfarin increased to 3 mg - inr only increased significantly after 2 aropax doses.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125260 **Seq:** 1 **Gender:** F
Reported: 25/02/1998 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 19/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

GASTROGEL (Other drug)			**Reason:**		
Oral Liquid	20.0	Millilitre	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		
CALTRATE (Other drug)			**Reason:**		
Tablet	2.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		
MOGADON (Other drug)			**Reason:**		
Tablet	0.0		Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		
MULTIVITAMINS (Other drug)			**Reason:**		
Tablet	1.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		

Laboratory Investigations:

Additional Information:

Patient had 3 inr tests after warfarin increased to 3 mg - inr only increased significantly after 2 aropax doses.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125449 **Seq:** 1 **Gender:** M
Reported: 02/03/1998 **Weight:** 70.00
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Suspected medication ceased

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 0.0 Daily Oral
Batch: **Started:** 01/02/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125455 **Seq:** 1 **Gender:** F
Reported: 02/03/1998 **Weight:** 68.00
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oculogyration Coordination abnormal		Eye rolling	Paroxetine reduced from 60mg to 20mg/d.

Medicine Details:

THIAMINE (Other drug) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CLONAZEPAM (Other drug) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/09/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125495 **Seq:** 1 **Gender:** F
Reported: 03/03/1998 **Weight:** 47.00
Hospitalisation: **Age:** 25Y
Onset Date: 02/02/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Bruxism Toothache	Severe	Unable to sleep	

Medicine Details:

MICROGYNON 50 (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/02/1998 **Stopped:** 27/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125595 **Seq:** 1 **Gender:** F
Reported: 05/03/1998 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: **DOB:** 23/07/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema Weight increased			Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125599 **Seq:** 1 **Gender:** F
Reported: 05/03/1998 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: **DOB:** 04/01/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/1996 **Stopped:** 28/09/1996

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/09/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125621 **Seq:** 1
Reported: 05/03/1998
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 65.00
Age: 25
DOB: 25/03/1972
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura	Required Specialist Consultation		

Medicine Details:

EPILIM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** 28/09/1997

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 04/07/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125674 **Seq:** 1 **Gender:** F
Reported: 10/03/1998 **Weight:** 60.00
Hospitalisation: **Age:** 29Y
Onset Date: 23/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eyelid ptosis Diarrhoea		Wide eyed appearance	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 22/02/1998 **Stopped:** 25/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medication commenced 18/2/98 at 1/2 tab and was increased to 1 tab 22/2/98.

Report Detail

Case Number: 125833 **Seq:** 1 **Gender:** F
Reported: 17/03/1998 **Weight:** 60.00
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Eye's blury on head movement	
Headache		Felt like head was exploding	
Insomnia		Waking up screaming	
Drug withdrawal syndrome			
Nightmare			Recomenced aropax

Medicine Details:

ISOTARD MC (Other drug) **Reason:** Diabetes mellitus
Injection 0.0 Subcutaneous
Batch: **Started:** **Stopped:**

INSULIN NOS (Other drug) **Reason:** Diabetes mellitus
Injection 0.0 Subcutaneous
Batch: **Started:** **Stopped:**

THYROXINE SODIUM (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/08/1997 **Stopped:** 24/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt restarted drug and symptoms settled the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125866 **Seq:** 1 **Gender:** M
Reported: 18/03/1998 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 20/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia Agitation		Muscle jerkiness	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/10/1997 **Stopped:** 21/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 125970 **Seq:** 1 **Gender:** M
Reported: 20/03/1998 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 28/10/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Antinuclear antibody positive Hepatic function abnormal		Shoulder region	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 01/09/1997 **Stopped:** 28/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Antinuclear factor ANA				1:320 speckled
	GGT = SGGT =		28/10/1997	154	
	SAP = ALP		28/10/1997	142	

Additional Information:

Resolution of symptoms within a week of ceasing aropax.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126041 **Seq:** 1 **Gender:** F
Reported: 23/03/1998 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrooesophageal reflux diseas Cough		Acid reflux	 Ceased aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 13/10/1997 **Stopped:** 23/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126042 **Seq:** 1 **Gender:** F
Reported: 23/03/1998 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 13/10/1997 **Stopped:** 23/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Report Detail

Case Number: 126106 **Seq:** 1 **Gender:** F
Reported: 23/03/1998 **Weight:** 75.00
Hospitalisation: **Age:** 66Y
Onset Date: 17/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Pruritus		Predominately on arms	Aropax ceased

Medicine Details:

MOGADON (Other drug) **Reason:**
0.5 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

RENITEC (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOCOR (Other drug) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126108 **Seq:** 1 **Gender:** F
Reported: 23/03/1998 **Weight:** 62.00
Hospitalisation: **Age:** 30Y
Onset Date: 01/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Dizziness Drug withdrawal syndrome Hyperhidrosis			Aropax recommenced

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/12/1996 **Stopped:** 30/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126151 **Seq:** 1 **Gender:** F
Reported: 25/03/1998 **Weight:** 59.00
Hospitalisation: **Age:** 26Y
Onset Date: 13/03/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nail disorder		5 broken nails in last 7-10 days	
Alopecia		Chunks of hair loss in shower	
Libido decreased		Loss of libido	
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 23/02/1998 **Stopped:** 25/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126162 **Seq:** 1 **Gender:** F
Reported: 25/03/1998 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126247 **Seq:** 1 **Gender:** F
Reported: 30/03/1998 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Diarrhoea			

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions occured on two seperate occassions within 2 hours of taking aropax.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126263 **Seq:** 1 **Gender:** F
Reported: 27/03/1998 **Weight:** 64.00
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 08/11/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Nausea Nightmare			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 30/04/1997 **Stopped:** 16/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax was restarted a week later for 3 days on 10mg, and a further 3 days on 5 mg. the symptoms resolved immediately and the patient was able to stop aropax 1 week after restarting.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126265 **Seq:** 1 **Gender:** F
Reported: 27/03/1998 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 23/01/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/11/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin	0 - 450	29/10/1997	495	
	Prolactin	0 - 450	23/01/1998	433	
	Radiololgy				Ultrasound breast - normal

Additional Information:

Noticed discomfort right breast october 1997. small amount of clear fluid from right breast. 1996 - on aropax for about 6 months, no galactorrhea reported then. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126312 **Seq:** 1 **Gender:** F
Reported: 01/04/1998 **Weight:** 78.00
Hospitalisation: **Age:** 31Y
Onset Date: 13/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Generalised and chronic	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 10/11/1997 **Stopped:** 16/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126407 **Seq:** 1
Reported: 03/04/1998
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 45.00
Age: 63
DOB: 05/02/1935
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare		Also wakes up frightened	

Medicine Details:

VENTOLIN (Other drug) **Reason:** Asthma
Inhalation 0.0 Inhalation
Batch: **Started:** **Stopped:**

NEULACTIL (Other drug) **Reason:** Other&unspecified epilepsy
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PREMARIN (Other drug) **Reason:** Menopausal symptoms
625.0 Microgram Daily
Batch: **Started:** **Stopped:**

PULMICORT (Other drug) **Reason:** Asthma
4.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original for full page drug allergy list.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126407 **Seq:** 1
Reported: 03/04/1998
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 45.00
Age: 63
DOB: 05/02/1935
Causality: Causality possible

Reaction Detail

Medicine Details:

RIVOTRIL (Other drug)			**Reason:**	Other&unspecified epilepsy	
	2.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
AROPAX (Suspected)			**Reason:**	Depression	
Tablet	10.0	Milligram	Daily	Oral	
Batch:	**Started:**	05/11/1997		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

See original for full page drug allergy list.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126408 **Seq:** 1 **Gender:** F
Reported: 03/04/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Dizziness Drug withdrawal syndrome Headache Nausea		Irritable	

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report came from patient. upon contacting dr, he had not been informed. reaction took place 3 days after ceasing aropax

Report Detail

Case Number: 126409 **Seq:** 1 **Gender:** F
Reported: 03/04/1998 **Weight:** 55.00
Hospitalisation: **Age:** 60Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Two lots of fasigyn x 4 given 2 days apart

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 16/11/1997 **Stopped:** CONTIN

EUHYPNOS (Suspected) **Reason:** Specific disorders of sleep
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 18/11/1997 **Stopped:** CONTIN

VALIUM (Suspected) **Reason:** Anxiety neurosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 18/11/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126472 **Seq:** 1
Reported: 07/04/1998
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 80.00
Age: 66Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms Hypertonia		Exacerbation of leg muscle cramps Myoclonic like muscle spasms at night.see	Aropax reduced to 10mg daily.

Medicine Details:

LITHIUM CARBONATE (Other drug)				**Reason:**	Depression
Tablet	750.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
OROXINE (Other drug)				**Reason:**	Myxedema
Tablet	100.0	Microgram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
AROPAX (Suspected)				**Reason:**	Depression
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Initially exacerbation of leg muscle cramps at night. this improved as dose was reduced to 10mg (from 20mg). now describes myoclonic like muscle spasms at night (2 months), affecting various muscle groups legs, arms, neck. doctor plans to gradually phase out aropax over 1-2 months.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126531 **Seq:** 1 **Gender:** F
Reported: 09/04/1998 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126532 **Seq:** 1 **Gender:** F
Reported: 09/04/1998 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 28/02/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Pollakiuria Somnolence Weight increased			Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 14/08/1997 **Stopped:** 23/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	0-50	28/02/1998	87 U/L	
	AST = SGOT	0-50	28/02/1998	71 U/L	

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126533 **Seq:** 1
Reported: 09/04/1998
Hospitalisation:
Onset Date: 31/03/1998
Outcome: Not yet recovered

Gender: F
Weight: 65.00
Age: 25Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126560 **Seq:** 1
Reported: 09/04/1998
Hospitalisation: Admitted to hospital
Onset Date: 08/03/1998
Outcome: Not yet recovered

Gender: F
Weight:
Age: 87Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Dizziness Epistaxis Orthostatic hypotension		Repeated falls	 Rest in bed.

Medicine Details:

MOTILIUM (Other drug)			**Reason:**	Nausea and vomiting	
Tablet	3.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PARACETAMOL (Other drug)			**Reason:**	Pain	
Tablet	6.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
ANGININE (Other drug)			**Reason:**		
Tablet	1.0	Dose Unspecified	Daily		Sublingual
Batch:	**Started:**			**Stopped:**	
KINSON (Suspected)			**Reason:**	Paralysis agitans	
Tablet	6.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126560 **Seq:** 1
Reported: 09/04/1998
Hospitalisation: Admitted to hospital
Onset Date: 08/03/1998
Outcome: Not yet recovered

Gender: F
Weight:
Age: 87Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 126566 **Seq:** 1
Reported: 09/04/1998
Hospitalisation: Admitted to hospital
Onset Date: 31/05/1997
Outcome: Recovered

Gender: F
Weight:
Age: 70Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Parkinson's disease	
Gait disturbance		Shuffling gait	
Headache			
Hypertonia			Melleril was ceased with subsequent marked improvement in parkinsonism symptoms. aropax was also ceased. headaches subsequently improved
Nausea			
Photophobia			
Tremor			

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Oral application 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

MODURETIC (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

PREPULSID (Other drug) **Reason:**
7.5 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

PREMARIN (Other drug) **Reason:** Menopausal symptoms
3.0 Microgram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126566 **Seq:** 1
Reported: 09/04/1998
Hospitalisation: Admitted to hospital
Onset Date: 31/05/1997
Outcome: Recovered

Gender: F
Weight:
Age: 70Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

MELLERIL (Suspected)			**Reason:**	Specific disorders of sleep	
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	29/08/1997
AROPAX (Suspected)			**Reason:**	Depression	
	10.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	30/08/1997

Laboratory Investigations:

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126667 **Seq:** 1 **Gender:** M
Reported: 14/04/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/03/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Priapism		Long-lasting erection.	

Medicine Details:

COZAAR (Suspected) **Reason:** Essential benign hypertension
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 26/03/1998 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 0.0 Daily Oral
Batch: **Started:** 26/03/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126742 **Seq:** 1 **Gender:** F
Reported: 17/04/1998 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema		Lip and tongue swelling	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 126761 **Seq:** 1 **Gender:** F
Reported: 17/04/1998 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 10/03/1998 **DOB:** 02/08/1920
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dehydration			
Diarrhoea			
Hyponatraemia			
Malaise			
Nausea			Fluid therapy
Vomiting			

Medicine Details:

MULTIVITAMINS (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

MULTI B COMPLEX (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

VENTOLIN NEBULES (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

IMDUR (Other drug) **Reason:**
60.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Digoxin level 4.91
	Sodium		10/03/1998	124	

Additional Information:

Report Detail

Case Number: 126761 **Seq:** 1 **Gender:** F
Reported: 17/04/1998 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 10/03/1998 **DOB:** 02/08/1920
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PERINDOPRIL (Other drug)			**Reason:**		
	4.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
DIGOXIN (Suspected)			**Reason:**		
Oral application	187.5	Microgram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	10/03/1998
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**		
	40.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
SPIRONOLACTONE (Suspected)			**Reason:**		
	50.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126761 **Seq:** 1 **Gender:** F
Reported: 17/04/1998 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 10/03/1998 **DOB:** 02/08/1920
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

FRUSEMIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126764 **Seq:** 1 **Gender:** M
Reported: 17/04/1998 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 12/02/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Disturbance in attention Hallucination Tremor		Low mental state. Unable to concentrate	Stopped all medication. diazepam 5-10mg prn oral given

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 1W

AURORIX (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:** 1W

MELLERIL (Suspected) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:** 1W

NEULACTIL (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:** 1W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126794 **Seq:** 1 **Gender:** M
Reported: 21/04/1998 **Weight:** 85.00
Hospitalisation: **Age:** 27Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy Fatigue		Quite emotionless	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/06/1997 **Stopped:** 15/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126795 **Seq:** 1 **Gender:** M
Reported: 21/04/1998 **Weight:** 85.00
Hospitalisation: **Age:** 27Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain	Required Visit to Doctor	Shooting pains in head	
Depression	Required Visit to Doctor		
Drug withdrawal syndrome			
Fatigue	Required Visit to Doctor		
Nausea	Required Specialist Consultation		Went from i tablet to 1/2 daily of aropax then ceased. now taking aurorix.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/06/1997 **Stopped:** 15/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126885 **Seq:** 1 **Gender:** M
Reported: 24/04/1998 **Weight:** 82.00
Hospitalisation: **Age:** 23Y
Onset Date: 31/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Anxiety Depression Fatigue Headache Increased appetite Somnolence Weight increased		Aches and pains generally	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126886 **Seq:** 1 **Gender:** F
Reported: 24/04/1998 **Weight:** 46.00
Hospitalisation: **Age:** 34
Onset Date: **DOB:** 03/10/1963
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Influenza like illness	Required Visit to Doctor	Flu like illness	
Somnolence	Required Visit to Doctor	Hypersomnia	
Asthenia	Required Visit to Doctor		
Confusional state	Required Specialist Consultation		
Drug withdrawal syndrome			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 25/10/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms one week after ceasing aropax, had reduced dose to 10mg for 3-4 days prior to ceasing. patient restarted aropax and symptoms ceased within a day. patient has not yet ceased aropax planning to slowly taper off 1/4 tablet each week until stops. patient is now well on the drug.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 126902 **Seq:** 1 **Gender:** F
Reported: 24/04/1998 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 28/10/1946
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Increased involuntary movement	Aropax ceased.

Medicine Details:

PERGOLIDE (Other drug) **Reason:**
Tablet 1.5 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

SINEMET CR (Other drug) **Reason:**
7.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

SINEMET (Other drug) **Reason:**
7.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** 28/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 127005 **Seq:** 1 **Gender:** M
Reported: 29/04/1998 **Weight:** 70.00
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 06/11/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction			

Medicine Details:

MELLERIL (Other drug) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 09/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127011 **Seq:** 1 **Gender:** F
Reported: 29/04/1998 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 16/03/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia Rash			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 13/03/1998 **Stopped:** 19/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127026 **Seq:** 1 **Gender:** F
Reported: 30/04/1998 **Weight:** 52.00
Hospitalisation: **Age:** 33Y
Onset Date: 24/03/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Severe	Waves of faintness as often as 2 0r 3 in 1/2	Withdrawal over 1 week of aropax 20mg daily to half dose.
Drug withdrawal syndrome			
Headache	Severe		
Nausea	Severe		

Medicine Details:

MICROGYNON 50 (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/09/1997 **Stopped:** 27/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Withdrawal of aropax 20mg was introduced 18/3/98, slowly over 1 week symptoms began from 24/3/98. patient reports always being sensitive to drugs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 127044 **Seq:** 1 **Gender:** M
Reported: 30/04/1998 **Weight:** 75.00
Hospitalisation: **Age:** 21Y
Onset Date: 31/03/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 14/06/1997 **Stopped:** 06/03/1998

SERZONE (Suspected) **Reason:** Depression
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 15/03/1998 **Stopped:** 18/04/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127072 **Seq:** 1 **Gender:** F
Reported: 01/05/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/04/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizzy	
Hypotension		Low b p 95/...	
Coordination abnormal		Unstable on feet	
Headache			Ceased aropax
Somnolence			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/02/1998 **Stopped:** 27/04/1998

SERZONE (Suspected) **Reason:** Depression
200.0 Milligram Daily
Batch: **Started:** 27/04/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127146 **Seq:** 1 **Gender:** F
Reported: 04/05/1998 **Weight:**
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 08/10/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of 11kg.	Ceased aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/09/1997 **Stopped:** 28/04/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127147 **Seq:** 1 **Gender:** F
Reported: 04/05/1998 **Weight:**
Hospitalisation: **Age:** 17Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Mania/hypomania	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 1M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127211 **Seq:** 1 **Gender:** F
Reported: 06/05/1998 **Weight:** 77.00
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Heart disease congenital Ventricular septal defect			Paroxetin ceased 6 weeks and 2 days into gestation. termination of pregnancy traumatic and undergoing further psychiatric care.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 01/01/1997 **Stopped:** 22/12/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				19 weeks as shown on ultra sound. single fetal cardiac ventricle. autopsy showed "double outlet left ventricle, doubly committed vsd, left sided hypoplastic aorta."

Additional Information:

Pt was using condoms as protection, foetus died 01/04/98. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127220 **Seq:** 1 **Gender:** U
Reported: 06/05/1998 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of 10kg	Ceased aropax, commenced fluoxetine

Medicine Details:

PROTHIADEN (Other drug) **Reason:**
25.0 Milligram As necessary
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 15/12/1996 **Stopped:** 28/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 127233 **Seq:** 1 **Gender:** F
Reported: 07/05/1998 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: 01/05/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Strabismus		Left convergent squint	Reaction persisted ater reducing to 10mg. ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 29/04/1998 **Stopped:** 04/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127325 **Seq:** 1
Reported: 13/05/1998
Hospitalisation:
Onset Date: 31/12/1996
Outcome: Not yet recovered

Gender: M
Weight: 85.00
Age: 48
DOB: 17/07/1948
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Ejaculation problems.	
Paraesthesia		Tingling of arms on and off in last 2 years.	Aropax reduced

Medicine Details:

SEREPAX (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127353 **Seq:** 1 **Gender:** F
Reported: 13/05/1998 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 21/07/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebral palsy Pulmonary artery stenosis conge Congenital hydrocephalus		Baby born with cerebral palsy Pulmonary valve stenosis	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
0.0 Oral
Batch: **Started:** 06/12/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Other data				Cardiac murmur, agenesis of corpus callosum.

Additional Information:

Mother commenced aropax at 24 weeks of pregnancy. has given birth to child with cerebral palsy. patient had 2 normal deliveries. paternal history of marfan's disease, pyloric stenosis.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127398 **Seq:** 1
Reported: 12/05/1998
Hospitalisation: Admitted to hospital
Onset Date: 31/12/1997
Outcome: Not yet recovered

Gender: M
Weight:
Age: 37Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction Abscess		Bowel obstruction	Bowel surgery, needed

Medicine Details:

RISPERIDONE (Suspected) **Reason:** Unspecified schizophrenia
4.0 Milligram Daily
Batch: **Started:** 01/11/1996 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 29/09/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127410 **Seq:** 1 **Gender:** F
Reported: 14/05/1998 **Weight:** 45.00
Hospitalisation: **Age:** 23Y
Onset Date: 08/05/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia Dry mouth Mydriasis Visual disturbance		Facial and jaw clenching	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

Batch: **Started:** 08/05/1998 **Stopped:** 08/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 127470 **Seq:** 1
Reported: 15/05/1998
Hospitalisation:
Onset Date: 17/03/1998
Outcome: Not yet recovered

Gender: F
Weight: 82.00
Age: 44Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability Palpitations		More teary, crying alot	 Decreased dose to 20mg daily.

Medicine Details:

DIAZEPAM (Other drug) **Reason:** Specific disorders of sleep

Tablet 5.0 Milligram As necessary Oral

Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 17/03/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127480 **Seq:** 1 **Gender:** M
Reported: 18/05/1998 **Weight:** 89.00
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Olanzapine reduced to 5mg on 01/05/98.

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Unspecified neurosis
10.0 Milligram Daily
Batch: **Started:** 01/05/1997 **Stopped:** CONTIN

ALPRAZOLAM (Suspected) **Reason:** Anxiety neurosis
1.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 01/10/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127567 **Seq:** 1 **Gender:** M
Reported: 18/05/1998 **Weight:**
Hospitalisation: **Age:** 75
Onset Date: **DOB:** 08/03/1923
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Corneal opacity			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 1.0 Dose Unspecified Daily Oral

Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Corneal opacity was linear, epithelial and moved across cornea over a period of 2 months and then disappeared. opacity was possibly herpetic, but did not appear to be so.

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127568 **Seq:** 1 **Gender:** F
Reported: 18/05/1998 **Weight:** 82.00
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 15/03/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ventricular septal defect Atrial septal defect Multiple congenital abnormalities Patent ductus arteriosus		Atrium and ventricle septum defect	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/06/1997 **Stopped:** 28/11/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother started on aropax treatment 2 weeks postconception and ceased aropax when she was 5 months pregnant. infant still under observation by paediatric cardiologist but doing well. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127569 **Seq:** 1 **Gender:** M
Reported: 18/05/1998 **Weight:** 0.00
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia Faecal incontinence Hepatitis cholestatic Weight decreased			

Medicine Details:

ALCOHOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily Oral
Batch: **Started:** 06/08/1997 **Stopped:**

HELIDAC (Suspected) **Reason:**
0.0 Daily Oral
Batch: **Started:** 13/03/1997 **Stopped:** 08/04/1997

XANAX (Suspected) **Reason:**
1.5 Milligram Daily
Batch: **Started:** 05/01/1992 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	ALT = SGPT		18/11/2005	308	
17/12/2002	AST = SGOT		18/11/2005	412	
17/12/2002	Bilirubin		18/11/2005	14	Direct bilirubin
17/12/2002	Bilirubin		18/11/2005	48	
17/12/2002	GGT = SGGT =		18/11/2005	1806	
17/12/2002	SAP = ALP		18/11/2005	179	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127569 **Seq:** 1 **Gender:** M
Reported: 18/05/1998 **Weight:** 0.00
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOCOR (Suspected) **Reason:** Othr&unspec metabolic diseases
10.0 Milligram Daily Oral
Batch: **Started:** 01/03/1998 **Stopped:**

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127589 **Seq:** 1 **Gender:** F
Reported: 18/05/1998 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: 27/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokinesia Gait disturbance		Unable to move lower limbs	

Medicine Details:

MADOPAR (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

SINEMET CR (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

COTAZYM-S FORTE (Other drug) **Reason:**
Tablet 6.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

OMEPRAZOLE (Other drug) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 127589 **Seq:** 1 **Gender:** F
Reported: 18/05/1998 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: 27/04/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

PROVERA (Other drug)			**Reason:**		
Tablet	5.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
DOMPERIDONE (Other drug)			**Reason:**		
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
AROPAX (Suspected)			**Reason:**	Depression	
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**	27/04/1998		**Stopped:**	30/04/1998

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127607 **Seq:** 1
Reported: 19/05/1998
Hospitalisation:
Onset Date: 31/01/1995
Outcome: Not yet recovered

Gender: F
Weight: 56.00
Age: 42Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction		See added info for description	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:** 28/08/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Orgasms modified immediatley on commencing medication and decreased physical (perineal muscle contractions) have persisted for 2 1/2 years after stopping aropax. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127666 **Seq:** 1 **Gender:** F
Reported: 22/05/1998 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 31/03/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Increase in pre existing leg spasms.	Changed aropax to serzone.

Medicine Details:

BACLOFEN (Other drug) **Reason:** Abnormal involuntary movement
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

TRISEQUENS (Other drug) **Reason:** Menopausal symptoms
1.0 Dose Unspecified Daily
Batch: **Started:** 25/03/1998 **Stopped:** CONTIN

OROXINE (Other drug) **Reason:** Myxedema
200.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/12/1997 **Stopped:** 25/04/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127721 **Seq:** 1 **Gender:** F
Reported: 22/05/1998 **Weight:** 53.00
Hospitalisation: **Age:** 34Y
Onset Date: 13/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		Pompholyx	Patient has stopped taking every 4th tablet of aropax.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 07/11/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127725 **Seq:** 1 **Gender:** F
Reported: 25/05/1998 **Weight:** 60.00
Hospitalisation: **Age:** 23
Onset Date: **DOB:** 24/10/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizzy spells	
Disturbance in attention		Lack of concentration	
Hyperhidrosis		Sweaty	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 01/10/1997 **Stopped:** 31/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127837 **Seq:** 1 **Gender:** M
Reported: 27/05/1998 **Weight:** 70.00
Hospitalisation: **Age:** 73Y
Onset Date: 04/05/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Nocturnal twitching	Aropax ceased

Medicine Details:

CARDIPRIN 100 (Other drug) **Reason:** Transient cereb isch no hypert
100.0 Milligram Daily
Batch: **Started:** 01/11/1997 **Stopped:**

LOSEC (Other drug) **Reason:** Other diseases of esophagus
20.0 Milligram Daily
Batch: **Started:** 28/02/1998 **Stopped:**

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127842 **Seq:** 1 **Gender:** F
Reported: 27/05/1998 **Weight:** 53.00
Hospitalisation: **Age:** 61Y
Onset Date: 13/05/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increas Aspartate aminotransferase incre			

Medicine Details:

PREMARIN (Other drug) **Reason:** Menopausal symptoms
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/01/1985 **Stopped:**

PROVERA (Other drug) **Reason:** Menopausal symptoms
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 01/01/1985 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/09/1997 **Stopped:** 25/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		13/05/1998	80	
	ALT = SGPT		20/05/1998	97	
	AST = SGOT		13/05/1998	52	
	AST = SGOT		20/05/1998	61	
	Immunology				Serology negative for hepatitis b and c. serology negative for autoimmune hepatitis.

Additional Information:

Nil alcohol. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 127874 **Seq:** 1 **Gender:** F
Reported: 27/05/1998 **Weight:** 70.00
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 19/02/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing Coordination abnormal Headache Nausea		Facial flushing Withdrawal syndrome.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/08/1994 **Stopped:** 01/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128014 **Seq:** 1 **Gender:** M
Reported: 01/06/1998 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 21/01/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome			Aropax ceased and restarted after 10 days.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/02/1998 **Stopped:** 28/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128090 **Seq:** 1 **Gender:** F
Reported: 05/06/1998 **Weight:** 37.00
Hospitalisation: **Age:** 16Y
Onset Date: 25/05/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination Anorexia Nausea		Visual hallucinations	 Ceased medication

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 25/05/1998 **Stopped:** 28/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of allergic response to penicillin.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128339 **Seq:** 1 **Gender:** F
Reported: 12/06/1998 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: 09/04/1998 **DOB:** 28/11/1962
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 19/02/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mild factor 8 defciency (inherited).

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128348 **Seq:** 1 **Gender:** F
Reported: 12/06/1998 **Weight:** 65.00
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 30/10/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Required Visit to Doctor	Weight increase to 6-7kg.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/12/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128351 **Seq:** 1 **Gender:** F
Reported: 15/06/1998 **Weight:** 96.00
Hospitalisation: **Age:** 39Y
Onset Date: 27/05/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Yawning		Uncontrollable, frequent yawning	Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 26/05/1998 **Stopped:** 28/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128370 **Seq:** 1 **Gender:** F
Reported: 15/06/1998 **Weight:** 70.00
Hospitalisation: **Age:** 49Y
Onset Date: 17/03/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Inappropriate antidiuretic hormon Nausea Vomiting		Confusional state	Fluid restriction and aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 10/03/1998 **Stopped:** 17/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Confirmed by appropriate serum & urinary electrolytes &

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128459 **Seq:** 1 **Gender:** M
Reported: 16/06/1998 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 01/02/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Severe		
Drug withdrawal syndrome	Severe		Resumed therapy with aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128462 **Seq:** 1
Reported: 15/06/1998
Hospitalisation: Admitted to hospital
Onset Date: 19/03/1998
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 78Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Dizziness Hypocalcaemia Hyponatraemia Hypophosphataemia			

Medicine Details:

DIGOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
62.5 Microgram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

CYPROHEPTADINE HYDROCHLORIDE (Suspected) **Reason:** Vertigo
0.0 As necessary
Batch: **Started:** **Stopped:** 19/03/1998

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 19/03/1998

PIROXICAM (Suspected) **Reason:** Unspecified arthritis
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 19/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Calcium	(2.15-2.6)	19/03/1998	1.76	
	Calcium	(2.15-2.6)	20/03/1998	1.76	
	Calcium	(2.15-2.6)	21/03/1998	1.94	
	Calcium	(2.15-2.6)	24/03/1998	-	
	Calcium	(2.15-2.6)	23/03/1998	2.05	
	Phosphate 1	(0.70-1.40)	19/03/1998	-	
	Phosphate 1	(0.70-1.40)	21/03/1998	0.32	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128462 **Seq:** 1
Reported: 15/06/1998
Hospitalisation: Admitted to hospital
Onset Date: 19/03/1998
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 78Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

CISAPRIDE (Suspected) **Reason:** Other diseases of esophagus
15.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 19/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Phosphate 1	(0.70-1.40)	20/03/1998	0.43	
	Phosphate 1	(0.70-1.40)	23/03/1998	0.23	
	Phosphate 1	(0.70-1.40)	24/03/1998	0.29	
	Potassium		19/03/1998	-	
	Potassium		21/03/1998	-	
	Potassium		25/03/1998	2.8	
	Potassium		24/03/1998	3	

Additional Information:

Report Detail

Case Number: 128462 **Seq:** 1
Reported: 15/06/1998
Hospitalisation: Admitted to hospital
Onset Date: 19/03/1998
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 78Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

DIGOXIN (Other drug)			**Reason:**	Otr&nos disord of heart rhythm	
	62.5	Microgram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	CONTIN
CYPROHEPTADINE HYDROCHLORIDE (Suspected)			**Reason:**	Vertigo	
	0.0		As necessary		
Batch:	**Started:**			**Stopped:**	19/03/1998
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
	20.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	19/03/1998
PIROXICAM (Suspected)			**Reason:**	Unspecified arthritis	
	10.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	19/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium		23/03/1998	3.2	
	Potassium		20/03/1998	-	
	Potassium		26/03/1998	4.5	
	Sodium	(135-145)	19/03/1998	117	
	Sodium	(135-145)	20/03/1998	117	
	Sodium	(135-145)	21/03/1998	117	
	Sodium	(135-145)	23/03/1998	122	

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128462 **Seq:** 1
Reported: 15/06/1998
Hospitalisation: Admitted to hospital
Onset Date: 19/03/1998
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 78Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

CISAPRIDE (Suspected) **Reason:** Other diseases of esophagus
15.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 19/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	(135-145)	24/03/1998	125	
	Sodium	(135-145)	25/03/1998	130	
	Sodium	(135-145)	26/03/1998	134	

Additional Information:

Report Detail

Case Number: 128513 **Seq:** 1 **Gender:** F
Reported: 18/06/1998 **Weight:** 70.00
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Abnormal liver function	

Medicine Details:

VITAMIN NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** CONTIN

TEGRETOL (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/09/1997 **Stopped:** 28/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		15/09/1997	20	
	ALT = SGPT		15/12/1997	54	
	ALT = SGPT		15/03/1998	30	
	ALT = SGPT		15/02/1998	126	
	ALT = SGPT		15/04/1998	24	
	GGT = SGGT =		15/09/1997	31	
	GGT = SGGT =		15/12/1997	76	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128513 **Seq:** 1 **Gender:** F
Reported: 18/06/1998 **Weight:** 70.00
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

VITAMIN NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** CONTIN

TEGRETOL (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/09/1997 **Stopped:** 28/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		15/02/1998	441	
	GGT = SGGT =		15/04/1998	55	
	GGT = SGGT =		15/03/1998	103	
	SAP = ALP		15/09/1997	116	
	SAP = ALP		15/12/1997	154	
	SAP = ALP		15/02/1998	229	
	SAP = ALP		15/03/1998	158	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128513 **Seq:** 1 **Gender:** F
Reported: 18/06/1998 **Weight:** 70.00
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

VITAMIN NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** CONTIN

TEGRETOL (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/09/1997 **Stopped:** 28/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		15/04/1998	156	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128520 **Seq:** 1 **Gender:** F
Reported: 18/06/1998 **Weight:** 60.00
Hospitalisation: **Age:** 24
Onset Date: **DOB:** 21/01/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death			

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/11/1997 **Stopped:** 28/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stopped taking aropax suddenly suffered withdrawal. foetus 6 weeks, ultrasound done at nine weeks, foetus still at 6 weeks development. subsequ- ent miscarriage followed several hours later on the 27/2/98. it apppears the sudden withdrawal from aropax may have triggered miscarrage. stopped taking medication at 6 weeks development which is when foetus also stopped developing. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128522 **Seq:** 1 **Gender:** F
Reported: 18/06/1998 **Weight:**
Hospitalisation: **Age:** 63Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flatulence	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient suffers from osteoperosis. sensitive to many medications ie: gluten and lactose intolerant.

Report Detail

Case Number: 128549 **Seq:** 1 **Gender:** F
Reported: 15/06/1998 **Weight:** 65.00
Hospitalisation: **Age:** 67Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain	Required Specialist Consultation		
Galactorrhoea	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/11/1997 **Stopped:** CONTIN

MURELAX (Suspected) **Reason:** Specific disorders of sleep
Tablet 7.5 Milligram Daily Oral
Batch: **Started:** 01/11/1997 **Stopped:**

PREMARIN (Suspected) **Reason:** Menopausal symptoms
Tablet 300.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

AMFAMOX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 128561 **Seq:** 1 **Gender:** M
Reported: 19/06/1998 **Weight:** 81.00
Hospitalisation: **Age:** 34Y
Onset Date: 28/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal failure acute			Iv rehydration

Medicine Details:

DECA-DURABOLIN (Other drug) **Reason:** Otr&unsp dis of musc,tend&fasc
Injection 0.0 Monthly Intramuscular
Batch: **Started:** **Stopped:**

PREDNISOLONE (Other drug) **Reason:** Otr&unsp dis of musc,tend&fasc
25.0 Milligram Daily
Batch: **Started:** 01/07/1997 **Stopped:** CONTIN

FOLIC ACID (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:** 30/01/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	<30 U/L	28/01/1998	7220	
	Bilirubin	<18 UMOL/L	28/01/1998	121	
	Creatinine	0.06-0.12	02/02/1998	0.45	
	Creatinine	0.06-0.12	23/02/1998	0.18	
	GGT = SGGT =	<35 U/L	28/01/1998	405	
	SAP = ALP	30-100 U/L	28/01/1998	206	

Additional Information:

Patient with hepatitis a. nephrologist thought arf was consistent with hepatorenal syndrome, however gastroenterologist believed it was drug related(paroxetine) the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 128561 **Seq:** 1 **Gender:** M
Reported: 19/06/1998 **Weight:** 81.00
Hospitalisation: **Age:** 34Y
Onset Date: 28/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

FLORINEF (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 01/10/1997 **Stopped:** 29/01/1998

Laboratory Investigations:

Additional Information:

Patient with hepatitis a. nephrologist thought arf was consistent with hepatorenal syndrome, however gastroenterologist believed it was drug related(paroxetine) the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128619 **Seq:** 1 **Gender:** F
Reported: 23/06/1998 **Weight:** 55.00
Hospitalisation: **Age:** 37Y
Onset Date: 25/02/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Night sweats	Paroxetine hcl ceased, patient recovered 2 weeks later.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 18/02/1998 **Stopped:** 05/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128671 **Seq:** 1 **Gender:** F
Reported: 26/06/1998 **Weight:** 63.00
Hospitalisation: **Age:** 66Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyuria			Aropax ceased

Medicine Details:

VALIUM (Other drug) **Reason:** Anxiety neurosis
Tablet 5.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 21/04/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128674 **Seq:** 1 **Gender:** F
Reported: 25/06/1998 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Has put on 1 stone	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/1996 **Stopped:** 28/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128675 **Seq:** 1 **Gender:** F
Reported: 25/06/1998 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Dizziness Nausea		Has been off aropax for two days Lightheadedness	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/1996 **Stopped:** 28/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128676 **Seq:** 1 **Gender:** F
Reported: 25/06/1998 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 22/11/1944
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 18/12/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128725 **Seq:** 1 **Gender:** M
Reported: 29/06/1998 **Weight:** 72.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Diarrhoea ++	Ceased aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 07/09/1997 **Stopped:** 28/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128733 **Seq:** 1 **Gender:** F
Reported: 29/06/1998 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: 20/06/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Spontaneous bruise - 1cm below left eye.	Aropax ceased

Medicine Details:

PREMARIN (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet 0.3 Milligram Daily Oral
Batch: **Started:** 20/05/1998 **Stopped:** 02/06/1998

PROVERA (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 20/05/1998 **Stopped:** 02/06/1998

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/06/1998 **Stopped:** 24/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				Fbe/coag studies n a d

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128776 **Seq:** 1 **Gender:** M
Reported: 24/06/1998 **Weight:** 56.00
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor		
Anxiety	Required Visit to Doctor		
Visual disturbance	Required Visit to Doctor		

Medicine Details:

RISPERDAL (Other drug) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

XANAX (Suspected) **Reason:**
Tablet 1.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt had overdose of xanax at the time pt started aropax. history; agitation and anxiety for 20 years.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128801 **Seq:** 1 **Gender:** F
Reported: 29/06/1998 **Weight:** 100.00
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 10/10/1949
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Visit to Doctor	Creepy crawley skin	

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

ADALAT (Other drug) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 01/10/1996 **Stopped:**

FENAC (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 01/04/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128801 **Seq:** 1
Reported: 29/06/1998
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 100.00
Age: 48
DOB: 10/10/1949
Causality: Causality possible

Reaction Detail

Medicine Details:

LIPITOR (Suspected)		**Reason:**	
	10.0 Milligram	Daily	
Batch:	**Started:** 01/11/1997		**Stopped:**
CLIMARA (Suspected)		**Reason:**	
	50.0 Milligram	Daily	
Batch:	**Started:** 01/10/1997		**Stopped:**

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128844 **Seq:** 1 **Gender:** F
Reported: 01/07/1998 **Weight:** 68.00
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 11/08/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menstrual disorder	Required Specialist Consultation	Period abnnormalities.	
Menorrhagia	Required Specialist Consultation		

Medicine Details:

ASPIRIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 128845 **Seq:** 1 **Gender:** M
Reported: 01/07/1998 **Weight:** 95.00
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pollakiuria			

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Oral application 150.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Obsessive compulsive neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128856 **Seq:** 1 **Gender:** F
Reported: 01/07/1998 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

OXAZEPAM (Suspected) **Reason:**
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128857 **Seq:** 1 **Gender:** U
Reported: 01/07/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Headache Hyperhidrosis Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was weaned of aropax-reduced to 10mg daily for 7 days before ceasing and 8 days later experienced symptoms. coffee worsened these effects.

Report Detail

Case Number: 128910 **Seq:** 1 **Gender:** F
Reported: 03/07/1998 **Weight:** 65.00
Hospitalisation: **Age:** 32Y
Onset Date: 25/06/1998 **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haemorrhage		Bled lots, difficult haemastasis.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 11/03/1998 **Stopped:** 25/06/1998

ZINC (Suspected) **Reason:**
1.0 Dose Unspecified Alternate days
Batch: **Started:** 01/06/1998 **Stopped:** 25/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequlae - very anaemic = hb - 75. allergies: maxolon - major convulsions.

Report Detail

Case Number: 128951 **Seq:** 1 **Gender:** F
Reported: 06/07/1998 **Weight:**
Hospitalisation: **Age:** 76
Onset Date: **DOB:** 13/10/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Required Specialist Consultation		

Medicine Details:

METFORMIN HYDROCHLORIDE (Interaction) **Reason:** Diabetes mellitus
0.0
Batch: **Started:** **Stopped:**

AROPAX (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 29/08/1997 **Stopped:** 06/02/1998

AMPRACE (Other drug) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CARDIZEM CD (Other drug) **Reason:**
Capsule 180.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Glycosylated		16/09/1997	8.5	
	Glycosylated		31/01/1998	10.6	

Additional Information:

Patient on multiple medications but changes in sugar levels only worsened when aropax started or stopped.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 128951 **Seq:** 1 **Gender:** F
Reported: 06/07/1998 **Weight:**
Hospitalisation: **Age:** 76
Onset Date: **DOB:** 13/10/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ISORDIL (Other drug)			**Reason:**	
Oral application	10.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
LANOXIN PG (Other drug)			**Reason:**	
Tablet	187.5	Microgram	Daily	Oral
Batch:	**Started:**			**Stopped:**
LASIX (Other drug)			**Reason:**	
Tablet	120.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

Patient on multiple medications but changes in sugar levels only worsened when aropax started or stopped.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129017 **Seq:** 1 **Gender:** F
Reported: 07/07/1998 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Stupor		Totally demented	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:** 72H

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129050 **Seq:** 1 **Gender:** F
Reported: 09/07/1998 **Weight:** 75.00
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura	Required Visit to Doctor	Bruising	Ceased aropax

Medicine Details:

TEMAZE (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/1998 **Stopped:** 04/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129052 **Seq:** 1 **Gender:** F
Reported: 09/07/1998 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 28/08/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Required Specialist Consultation		

Medicine Details:

TRIFEME 28 (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

THYROXINE SODIUM (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/11/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129257 **Seq:** 1 **Gender:** F
Reported: 15/07/1998 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation	Required Visit to Doctor	Feels out of sink with everything	
Nightmare	Required Visit to Doctor	Waking up with nightmares	
Drug withdrawal syndrome	Required Visit to Doctor		
Hallucination	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Muscle twitching	Required Visit to Doctor		

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
0.0 As necessary
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 31/01/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129257 **Seq:** 1 **Gender:** F
Reported: 15/07/1998 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Visit to Doctor		
Tremor	Required Visit to Doctor		Had to go back on aropax after 2 weeks.

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
0.0 As necessary
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 31/01/1997

Laboratory Investigations:

Additional Information:

the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129258 **Seq:** 1 **Gender:** F
Reported: 15/07/1998 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tooth disorder	Required Visit to Doctor	Teeth not as strong have hairline cracks.	
Dizziness	Required Visit to Doctor		
Dry skin	Required Visit to Doctor		
Hypotension	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129287 **Seq:** 1 **Gender:** F
Reported: 17/07/1998 **Weight:** 50.00
Hospitalisation: **Age:** 20
Onset Date: **DOB:** 02/12/1977
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Required Visit to Doctor		Therapy changed to luvox.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 22/10/1997 **Stopped:** 16/12/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Concomitant maihunana use.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129425 **Seq:** 1 **Gender:** F
Reported: 23/07/1998 **Weight:** 70.00
Hospitalisation: **Age:** 32Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome			Aropax dose tapered gradually

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** 28/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129519 **Seq:** 1 **Gender:** M
Reported: 24/07/1998 **Weight:** 80.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Required Specialist Consultation	Jaw tremble	

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129520 **Seq:** 1 **Gender:** M
Reported: 24/07/1998 **Weight:** 70.00
Hospitalisation: **Age:** 31Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure	Required Specialist Consultation		

Medicine Details:

EPILIM (Other drug) **Reason:** Other&unspecified epilepsy
Oral application 1.0 Gram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 2.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129693 **Seq:** 1 **Gender:** F
Reported: 28/07/1998 **Weight:** 60.00
Hospitalisation: **Age:** 35Y
Onset Date: 07/05/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Multiple large bruises 10cm x 5cm.	Aropax ceased and pt started

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 09/04/1998 **Stopped:** 21/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129730 **Seq:** 1 **Gender:** F
Reported: 30/07/1998 **Weight:**
Hospitalisation: Treated in outpatient department only. **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria Tongue oedema		Widespread urticaria	Unspecified treatment given. aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax tablet given two days later and reaction reoccurred.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129731 **Seq:** 1 **Gender:** F
Reported: 30/07/1998 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 10/07/1962
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash	Required Visit to Doctor	Itchy legs, stomach, arms with patches.	Aropax = 4 months. initially on 20mg/day and titrated up to 40mg 1 month ago. reduced back to 20mg 2 weeks ago and rash started 2 days ago.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/02/1998 **Stopped:** 28/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129814 **Seq:** 1 **Gender:** F
Reported: 31/07/1998 **Weight:** 42.00
Hospitalisation: **Age:** 28Y
Onset Date: 27/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Hyponatraemia			 Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** 24/07/1998 **Stopped:** 27/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		27/07/1998	123	
	Sodium		28/07/1998	131	

Additional Information:

Pt has background of anorexia nervosa.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129825 **Seq:** 1 **Gender:** F
Reported: 31/07/1998 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia	Required Visit to Doctor		
Weight increased	Required Visit to Doctor		Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** 28/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129854 **Seq:** 1 **Gender:** F
Reported: 03/08/1998 **Weight:** 56.00
Hospitalisation: **Age:** 48Y
Onset Date: 24/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Periorbital oedema Angioedema Dysphagia Dyspnoea		Swelling of left eye. Swelling of throat	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 17/07/1998 **Stopped:** 24/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

First contact with an ssri.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 129933 **Seq:** 1 **Gender:** F
Reported: 06/08/1998 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: 04/03/1998 **DOB:** 19/06/1946
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Required Visit to Doctor		Aropax ceased and pt started prothiaden
Depression	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/03/1997 **Stopped:** 28/04/1998

ZOCOR (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130038 **Seq:** 1 **Gender:** F
Reported: 10/08/1998 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Same reaction occurred with 20mg aropax.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130075 **Seq:** 1 **Gender:** F
Reported: 13/08/1998 **Weight:** 57.00
Hospitalisation: **Age:** 55Y
Onset Date: 25/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mydriasis	Severe		Ceased aropax

Medicine Details:

OROXINE (Other drug) **Reason:**
50.0 Microgram Daily
Batch: **Started:** 01/01/1996 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** 25/07/1998 **Stopped:** 25/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130088 **Seq:** 1 **Gender:** F
Reported: 13/08/1998 **Weight:**
Hospitalisation: **Age:** 59Y
Onset Date: 03/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema Myalgia Headache		Face and neck swelling Sore muscles in neck.	

Medicine Details:

VITAMINS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/07/1998 **Stopped:** 03/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130120 **Seq:** 1 **Gender:** F
Reported: 14/08/1998 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Somnolence Tremor			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** 28/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced similar reactions to aropax on both series that drug was taken. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130253 **Seq:** 1 **Gender:** F
Reported: 12/08/1998 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flatulence		Abdominal distension	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130315 **Seq:** 1 **Gender:** F
Reported: 19/08/1998 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 05/04/1956
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		"flushes/surges" in head	Aropax ceased and four days later placed on 25mg zoloft for 2 days and on 03/08/98 was placed on xanax 0.5mg tds. treated with phenergan.
Muscle twitching		Muscle twitches	
Confusional state			
Dizziness			
Hypertonia			
Pruritus			
Rash			

Medicine Details:

NUROFEN (Other drug) **Reason:**
2.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 10/05/1998 **Stopped:** 26/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130316 **Seq:** 1 **Gender:** F
Reported: 19/08/1998 **Weight:** 75.00
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 10/08/1946
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Disorganised, spending lots of money, poor	
Affect lability		Labile affect	
Insomnia		Lack of sleep	
Mania		Mania symptoms	Aropax ceased
Speech disorder		Pressured speach	
Delusion			
Hyperkinesia			

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 19/10/1997 **Stopped:** 29/10/1997

AROPAX (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 19/10/1997 **Stopped:** 29/10/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130398 **Seq:** 1 **Gender:** M
Reported: 21/08/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Required Specialist Consultation	Inability to stand up	
Visual disturbance	Required Specialist Consultation		Aropax and stelazine ceased.

Medicine Details:

AROPAX (Suspected)			**Reason:**	
Tablet	20.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
STELAZINE (Suspected)			**Reason:**	
Oral application	5.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130408 **Seq:** 1 **Gender:** F
Reported: 24/08/1998 **Weight:** 55.00
Hospitalisation: **Age:** 32Y
Onset Date: 06/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			
Dizziness			
Drug withdrawal syndrome			
Flushing			
Hyperhidrosis			
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 22/10/1996 **Stopped:** 28/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Slow reduction over six weeks, 40mg --> 10mg. symptoms began when started on 10mg second daily. (cleared within 48 hours of recommencing aropax 20mg).

Report Detail

Case Number: 130550 **Seq:** 1 **Gender:** M
Reported: 28/08/1998 **Weight:** 83.00
Hospitalisation: **Age:** 44
Onset Date: 10/08/1998 **DOB:** 03/06/1954
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Specialist Consultation	Abdominal burning	
Dysuria	Required Specialist Consultation	Difficulty in urination	
Face oedema	Required Specialist Consultation	Swollen right side of face	Stopped aropax.
Visual disturbance	Required Specialist Consultation	Vision blurred right eye	

Medicine Details:

VITAMINS (Other drug) **Reason:**
Oral application 1.2 Gram Daily Oral
Batch: **Started:** **Stopped:**

MINERALS (Other drug) **Reason:**
Oral application 1.2 Gram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 10/08/1998 **Stopped:** 10/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130550 **Seq:** 1 **Gender:** M
Reported: 28/08/1998 **Weight:** 83.00
Hospitalisation: **Age:** 44
Onset Date: 10/08/1998 **DOB:** 03/06/1954
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Specialist Consultation		
Muscle twitching	Required Specialist Consultation		
Paraesthesia	Required Specialist Consultation		

Medicine Details:

VITAMINS (Other drug) **Reason:**
Oral application 1.2 Gram Daily Oral
Batch: **Started:** **Stopped:**

MINERALS (Other drug) **Reason:**
Oral application 1.2 Gram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 10/08/1998 **Stopped:** 10/08/1998

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130593 **Seq:** 1 **Gender:** M
Reported: 27/08/1998 **Weight:** 60.00
Hospitalisation: **Age:** 35Y
Onset Date: 13/08/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia Drug withdrawal syndrome	Severe	Severe retrograde amnesia	Dr advised pt to recommence paroxetine

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/10/1997 **Stopped:** 01/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt initiated withdrawal. symptoms began ~1 week after cessation. dr advised pt to recommence paroxetine 20mg/day. no recovery after 3 weeks of drug free period. anxiety attacks returned.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130770 **Seq:** 1 **Gender:** F
Reported: 03/09/1998 **Weight:** 60.00
Hospitalisation: **Age:** 31Y
Onset Date: 03/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/06/1998 **Stopped:** 28/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130804 **Seq:** 1 **Gender:** F
Reported: 07/09/1998 **Weight:** 50.00
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tongue oedema		Swollen tongue	Paroxetine ceased and changed to luvox after a three

Medicine Details:

XANAX (Other drug) **Reason:**
Tablet 500.0 Microgram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130818 **Seq:** 1 **Gender:** F
Reported: 07/09/1998 **Weight:** 65.00
Hospitalisation: **Age:** 53Y
Onset Date: 31/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance		Electric shock down limbs - trembling	
Headache		Headache felt like "brain was shaking"	
Agitation			
Drug withdrawal syndrome	Severe		
Hypoaesthesia			
Tremor			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:** 20/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130851 **Seq:** 1 **Gender:** F
Reported: 02/09/1998 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 06/06/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction	Required Specialist Consultation	Not loss of libido but physical disturbance	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130857 **Seq:** 1 **Gender:** M
Reported: 02/09/1998 **Weight:**
Hospitalisation: **Age:** 41Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Required Specialist Consultation	Worsening of tinnitus	Aropax tapered to 10mg and then ceased
Somnolence	Required Specialist Consultation		
Yawning	Required Specialist Consultation		

Medicine Details:

DIAZEPAM (Other drug) **Reason:** Anxiety neurosis
Tablet 2.5 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 08/07/1998 **Stopped:** 21/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt has history of niddm and tinnitus

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130858 **Seq:** 1 **Gender:** M
Reported: 02/09/1998 **Weight:**
Hospitalisation: **Age:** 70
Onset Date: **DOB:** 12/10/1927
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Dysphagia		Shaking violently	Aropax ceased

Medicine Details:

BECLOFORTE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

VENTOLIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 16/08/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt got teeth pain from losec

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 130896 **Seq:** 1
Reported: 07/09/1998
Hospitalisation: Admitted to hospital
Onset Date: 18/06/1998
Outcome: Not yet recovered

Gender: M
Weight:
Age: 77Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dehydration	Required Visit to Doctor		Paroxetine ceased
Orthostatic hypotension	Required Visit to Doctor		

Medicine Details:

FERRO-GRADUMET (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PROPINE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

BETAGAN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

COLGOUT (Other drug) **Reason:** Gout
Tablet 500.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Admitted to hospital 08/04/98 with postural drop - resistant to iv fluid therapy. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 130896 **Seq:** 1
Reported: 07/09/1998
Hospitalisation: Admitted to hospital
Onset Date: 18/06/1998
Outcome: Not yet recovered

Gender: M
Weight:
Age: 77Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ZINCAPS (Other drug)			**Reason:**		
Capsule	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:** 01/03/1998			**Stopped:**	
ASCORBIC ACID (Other drug)			**Reason:**		
Oral application	500.0	Milligram	Daily		Oral
Batch:	**Started:** 01/03/1998			**Stopped:**	
ASPIRIN (Other drug)			**Reason:**		
Oral application	0.5	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
AROPAX (Suspected)			**Reason:**	Depression	
Tablet	40.0	Milligram	Daily		Oral
Batch:	**Started:** 01/01/1998			**Stopped:**	

Laboratory Investigations:

Additional Information:

Admitted to hospital 08/04/98 with postural drop - resistant to iv fluid therapy. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131024 **Seq:** 1 **Gender:** F
Reported: 09/09/1998 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Goitre Tremor		Thyroide enlargement despite normal tft	 Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131025 **Seq:** 1 **Gender:** M
Reported: 09/09/1998 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction Anorexia Constipation Ejaculation failure Somnolence Tremor		Difficulty maintaining an erection	Aropax started 06/05/98 1 tablet daily for 14 days. increased to 2 tablets daily for 5 days then reduced to 1 tablet for 2 days and the no tablets for three days

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 06/05/1998 **Stopped:** 07/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131028 **Seq:** 1 **Gender:** F
Reported: 09/09/1998 **Weight:** 67.00
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Couldn't do simple judgement /decisions	
Fatigue	Severe	Extreme fatigue	Aropax ceased
Agitation	Severe	Extrme restlessness	
Hypertonia	Severe	Neck stiffness	
Anxiety	Severe	Severe anxiety attacks	
Insomnia	Severe		
Nausea			

Medicine Details:

MICROGYNON 30 (Other drug) **Reason:**
Pill 30.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 16/06/1998 **Stopped:** 19/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had nasty reaction to prozac when took it 2 years ago.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131037 **Seq:** 1 **Gender:** M
Reported: 09/09/1998 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Hypertension	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous mild labile hypertention, not just prior to beginning aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131040 **Seq:** 1 **Gender:** F
Reported: 10/09/1998 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Specialist Consultation	Creepy-crawly feeling on skin.	
Palpitations	Required Specialist Consultation		Aropax ceased.
Vomiting	Required Specialist Consultation		

Medicine Details:

HYGROTON (Other drug) **Reason:** Edema and dropsy
Tablet 0.0 As necessary Oral
Batch: **Started:** L TERM **Stopped:**

TIMOLOL MALEATE (Other drug) **Reason:** Unspecified glaucoma
Eye Drops 4.0 Dose Unspecified Daily Ophthalmic
Batch: **Started:** L TERM **Stopped:**

PROGYNOVA (Other drug) **Reason:** Menopausal symptoms
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 03/07/1998 **Stopped:** 04/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to pethidine.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131127 **Seq:** 1 **Gender:** F
Reported: 03/09/1998 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 19/03/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Weight increased		Sleepiness	

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131129 **Seq:** 1 **Gender:** F
Reported: 03/09/1998 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 19/03/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Nausea			Aropax restarted and slowly

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131135 **Seq:** 1 **Gender:** F
Reported: 11/09/1998 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Developed a shaking sensation all over	Pt taking half tablet developed symptoms, after one week dose was increased to one tablet. symptoms became worse, so aropax was ceased after another week

Medicine Details:

TILCOTIL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZANTAC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 15/08/1998 **Stopped:** 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt suffering from arthritis, before taking aropax, felt she was shaking but not physically doing it.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131197 **Seq:** 1 **Gender:** F
Reported: 17/09/1998 **Weight:** 78.00
Hospitalisation: **Age:** 39Y
Onset Date: 06/09/1998 **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Hot flush Palpitations Tinnitus Vertigo			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** 08/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On withdrawing the aropax the symptoms started even though patient was on half a tablet at the time. happened previous time patient attempted to stop. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131238 **Seq:** 1
Reported: 03/09/1998
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 76.00
Age: 63
DOB: 11/09/1934
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Severe restless legs at night time	Propranolol 80mg bd, clonazepam 0.5mg nocte

Medicine Details:

OESTROGENS NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

MODURETIC (Other drug) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/08/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt used aropax in 1997 for nine months - came off for similar reason. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131266 **Seq:** 1 **Gender:** F
Reported: 16/09/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Choking feeling	
Gait disturbance	Required Visit to Doctor	Could not walk	
Muscle twitching	Required Visit to Doctor	Neck spasms	
Hypoaesthesia		Numbness of face	
Asthenia			
Dizziness	Required Visit to Doctor		Ceased aropax. oral prednisolone 30mg, atrovent by nebuliser
Paraesthesia			

Medicine Details:

LOSEC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

NORVASC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 24/08/1998 **Stopped:** 25/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 131266 **Seq:** 1 **Gender:** F
Reported: 16/09/1998 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor		

Medicine Details:

LOSEC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

NORVASC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 24/08/1998 **Stopped:** 25/08/1998

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131274 **Seq:** 1 **Gender:** M
Reported: 16/09/1998 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 13/09/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Jerks in legs at night (sometimes)	
Hyperhidrosis		Little sweaty on forehead.	
Tremor		Slight shaking	
Dry mouth			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 03/07/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131281 **Seq:** 1
Reported: 16/09/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 40Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Drug ineffective			Dose of aropax gradually

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 01/04/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Severe relapse of depression after taking aropax successfully for 2 years. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 131516 **Seq:** 1 **Gender:** F
Reported: 25/09/1998 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 28/08/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia Hypertension Malaise Serotonin syndrome Tachycardia			

Medicine Details:

ARIMA (Interaction) **Reason:** Depression
600.0 Milligram Daily
Batch: **Started:** 01/02/1998 **Stopped:** 26/08/1998

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 28/08/1998 **Stopped:** 28/08/1998

TEMAZEPAM (Interaction) **Reason:** Specific disorders of sleep
20.0 Milligram Daily
Batch: **Started:** 28/08/1998 **Stopped:** 28/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131532 **Seq:** 1 **Gender:** F
Reported: 25/09/1998 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 09/04/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia	Required Specialist Consultation	Burning in the stomach	
Yawning	Required Specialist Consultation	Desire for yawning	
Dysphagia	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/09/1998 **Stopped:** 09/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131533 **Seq:** 1 **Gender:** F
Reported: 25/09/1998 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism	Required Visit to Doctor	Involuntary crunching of teeth	
Tremor	Required Visit to Doctor	Jittery/shivering feeling	Aropax ceased
Dystonia	Required Visit to Doctor	Slightly dystonic	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 05/09/1998 **Stopped:** 07/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131551 **Seq:** 1 **Gender:** M
Reported: 28/09/1998 **Weight:** 80.00
Hospitalisation: **Age:** 49Y
Onset Date: 15/09/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction Constipation		Erectile dysfunction	Therapy changed back to

Medicine Details:

NORVASC (Other drug) **Reason:**

0.0

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131567 **Seq:** 1 **Gender:** F
Reported: 28/09/1998 **Weight:**
Hospitalisation: **Age:** 56Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Pruritus		4 red macules	Topical ointment

Medicine Details:

SEREPAX (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131574 **Seq:** 1 **Gender:** M
Reported: 28/09/1998 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash	Required Specialist Consultation	Itchy small red macules consistently	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131589 **Seq:** 1 **Gender:** M
Reported: 29/09/1998 **Weight:** 95.00
Hospitalisation: **Age:** 46Y
Onset Date: 18/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Peripheral ischaemia	Severe	Severe chills, shakes	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt has used prozac previously with no problems.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131608 **Seq:** 1 **Gender:** F
Reported: 30/09/1998 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep disorder Agitation Anorexia Anxiety Dizziness Drug withdrawal syndrome Intra-uterine death Nausea Thinking abnormal		Sleep interuption	

Medicine Details:

NORIMIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/08/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose of aropax reduced from 60mg to 30mg and patient had reactions. also on contraceptive pill which failed twice. patient suffered a miscarriage on both occasions. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131639 **Seq:** 1 **Gender:** M
Reported: 30/09/1998 **Weight:**
Hospitalisation: **Age:** 11Y
Onset Date: 13/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Excessive bruising after injury.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 16/06/1998 **Stopped:** 14/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				Coagulation profile 15/7/98: aptt 45 seconds (normal 25 - 38 secs) all other tests normal. repeat coagulation profile on 27/7/98 has returned to normal

Additional Information:

Aropax was well tolerated until child injured --> bruised right arm, which by the next day)13/7/98) had extended to cover his whole arm, far exceeding the actual area of injury.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131640 **Seq:** 1 **Gender:** M
Reported: 30/09/1998 **Weight:**
Hospitalisation: **Age:** 11Y
Onset Date: 16/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise Drug withdrawal syndrome Muscle spasms Nausea		Became physically ill	

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 10/06/1998 **Stopped:** 14/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131733 **Seq:** 1 **Gender:** M
Reported: 02/10/1998 **Weight:**
Hospitalisation: **Age:** 54
Onset Date: **DOB:** 22/08/1944
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Anaemia Neutropenia Pancytopenia Pyrexia Red blood cell sedimentation rate		Body pains	Aropax was withdrawn over eight days and switched over to cipramil

Medicine Details:

DESERIL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

RANITIDINE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 12/09/1995 **Stopped:** 09/03/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Erythrocyte	(1-20)	25/06/1998	30	
	Haemoglobin	(135-180)	16/06/1998	117	
	Haemoglobin	(135-180)	29/07/1998	106	
	Neutrophils	(2.0-7.5)	29/07/1998	1.6	
	Red blood cells	(4.2-6.0)	16/06/1998	3.4	
	Red blood cells	(4.2-6.0)	29/07/1998	3.1	
	White blood cells	(4.0-11.0)	29/07/1998	3.1	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131875 **Seq:** 1
Reported: 09/10/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 70.00
Age: 54Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Required Visit to Doctor	Mania requiring hospitalisation	

Medicine Details:

NEULACTIL (Other drug) **Reason:** Explosive personality disorder

Tablet 2.0 Milligram As necessary Oral

Batch: **Started:** 01/08/1998 **Stopped:**

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/08/1998 **Stopped:** 28/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt has an 8 year history of alzheimers disease. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131876 **Seq:** 1 **Gender:** F
Reported: 09/10/1998 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 15/02/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Dizziness Drug withdrawal syndrome		Loss of balance upon sudden movements	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 28/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt had not recovered on day of report the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131880 **Seq:** 1 **Gender:** M
Reported: 01/10/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Depression			

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Arapax made patient feel more depressed that he had to have the rifle removed from the house.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131887 **Seq:** 1 **Gender:** F
Reported: 08/10/1998 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 26/09/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Tremor	Severe Severe	Rigidity in face and neck.	Ceased aropax, given imi cogentin 2mg/2ml and

Medicine Details:

XANAX (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

COGENTIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 29/06/1998 **Stopped:** 29/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 131899 **Seq:** 1 **Gender:** F
Reported: 08/10/1998 **Weight:** 84.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Required Visit to Doctor		

Medicine Details:

RENITEC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131928 **Seq:** 1 **Gender:** F
Reported: 12/10/1998 **Weight:** 60.00
Hospitalisation: **Age:** 45Y
Onset Date: 02/10/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Petechiae, purpura and bruising	Aropax ceased

Medicine Details:

LUVOX (Other drug) **Reason:** Anxiety neurosis
0.5 Dose Unspecified As necessary
Batch: **Started:** 01/03/1998 **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 01/03/1998 **Stopped:** 06/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 131963 **Seq:** 1 **Gender:** F
Reported: 12/10/1998 **Weight:** 82.00
Hospitalisation: **Age:** 43Y
Onset Date: 28/05/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance		Sensory loss from knees to feet	
Amnesia		Short term memory loss	
Depersonalisation			
Drug withdrawal syndrome			Daily dosage restarted, then very very slow reduction of

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 01/12/1997 **Stopped:** 25/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132031 **Seq:** 1 **Gender:** F
Reported: 14/10/1998 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 10/10/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Dizziness Drug withdrawal syndrome Tremor			All symptoms resolved on recommencing aropax.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132059 **Seq:** 1
Reported: 16/10/1998
Hospitalisation:
Onset Date: 16/09/1998
Outcome: Not yet recovered

Gender: F
Weight: 39.00
Age: 55Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Tremor		Severe cogwheel rigidity Visible parkinsonism tremor.	

Medicine Details:

LITHICARB (Other drug) **Reason:** Ment dis asso w circul disturb
750.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 17/07/1998 **Stopped:** 16/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Severity decreasing but still observable.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132093 **Seq:** 1 **Gender:** F
Reported: 15/10/1998 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Abnormal body movements	
Dystonia		Clenched jaw	
Drug withdrawal syndrome neona			
Muscle twitching			
Oculogyration			
Torticollis			

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on aropax for approx. first 10 weeks of pregnancy. aropax restarted at approx. 4 months and continued right through until birth. mother discontinued aropax after birth and commenced breastfeeding 6 days after birth.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132116 **Seq:** 1
Reported: 19/10/1998
Hospitalisation:
Onset Date: 20/06/1998
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 39Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Large bruises 3 weeks after commencing	Both treatments continued. coagulator given and fbc

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 28/05/1998 **Stopped:** CONTIN

BETALOC (Suspected) **Reason:** Palpitation
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 20/05/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 132120 **Seq:** 1 **Gender:** F
Reported: 19/10/1998 **Weight:** 80.00
Hospitalisation: **Age:** 55Y
Onset Date: 07/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Nightmare Pollakiuria		Interupted sleep	

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/10/1998

CIPRAMIL (Interaction) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 07/10/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132237 **Seq:** 1 **Gender:** M
Reported: 21/10/1998 **Weight:** 93.00
Hospitalisation: **Age:** 54Y
Onset Date: 12/10/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction Insomnia		Sexual dysfunction	

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

ZOTON (Other drug) **Reason:** Other diseases of esophagus
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 14/09/1998 **Stopped:**

ATENOLOL (Other drug) **Reason:** Essential benign hypertension
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 09/09/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132241 **Seq:** 1 **Gender:** F
Reported: 22/10/1998 **Weight:** 80.00
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			
Tinnitus	Severe		
Vertigo	Severe		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 18M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt restarted medication with instant relief. has tried a gradual withdrawal slowly to 0.5 df alt days and after 3 weeks of reduced dose stopped. got same reaction next day.

Report Detail

Case Number: 132403 **Seq:** 1 **Gender:** F
Reported: 29/10/1998 **Weight:**
Hospitalisation: **Age:** 56Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Required Specialist Consultation	Pulse in the head	
Dizziness	Required Specialist Consultation		
Nausea	Required Specialist Consultation		Aropax ceased

Medicine Details:

MAXOLON (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 07/10/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt is also on hrt. pt has a long history of chronic nausea, dizziness and a woozy feeling in the head. she also has chronic fatigue syndrome.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132420 **Seq:** 1 **Gender:** F
Reported: 26/10/1998 **Weight:** 67.00
Hospitalisation: **Age:** 77Y
Onset Date: 17/10/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus Visual disturbance Apathy Dizziness Fatigue		Pinging noise in ears. Wavy lines in front of eyes.	Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 01/04/1998 **Stopped:** 15/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 132523 **Seq:** 1 **Gender:** F
Reported: 28/10/1998 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 02/11/1949
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Required Visit to Doctor		
Dizziness	Required Visit to Doctor		
Insomnia	Required Visit to Doctor		Ceased aropax.

Medicine Details:

PEPCIDINE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 05/09/1998 **Stopped:** 13/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy reaction to augmentin-> severe abdomnial pain, vomiting and diarrhoea.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132763 **Seq:** 1 **Gender:** F
Reported: 03/11/1998 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Required Visit to Doctor	Nocturnal enuresis	
Pollakiuria	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 132772 **Seq:** 1 **Gender:** F
Reported: 03/11/1998 **Weight:** 65.00
Hospitalisation: **Age:** 26Y
Onset Date: 22/10/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syndactyly		Right foot 4th/5th toes	

Medicine Details:

DUCENE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

MOGADON (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

XANAX (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** 01/12/1997 **Stopped:** 28/02/1998

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 08/01/1998 **Stopped:** 28/02/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother on antidepressants very early pregnancy. baby born with mild birth defect. right foot 4th/5th toes syndactyly with small extra digit fused also. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132796 **Seq:** 1 **Gender:** F
Reported: 05/11/1998 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 01/10/1945
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Required Specialist Consultation	Occasional lingual or bucco-lingual	

Medicine Details:

AROPAX (Suspected)		**Reason:** Depression		
Tablet	20.0 Milligram	Daily	Oral	
Batch:	**Started:** 07/04/1998		**Stopped:**	CONTIN
SERENACE (Suspected)		**Reason:**		
Tablet	20.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/04/1998		**Stopped:** 28/05/1998	
HALOPERIDOL (Suspected)		**Reason:** Headache		
Injection	5.0 Milligram	Alternate days	Intravenous	
Batch:	**Started:**		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132799 **Seq:** 1 **Gender:** F
Reported: 05/11/1998 **Weight:** 62.00
Hospitalisation: **Age:** 55Y
Onset Date: 31/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence	Required Visit to Doctor		Aropax subsequently ceased

Medicine Details:

PANADEINE FORTE (Other drug)			**Reason:**		
Tablet	1.0	Dose Unspecified	As necessary	Oral	
Batch:	**Started:**			**Stopped:**	
MS CONTIN (Other drug)			**Reason:**		
Oral application	20.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**		
Tablet	5.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
AROPAX (Suspected)			**Reason:**		
Tablet	40.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132976 **Seq:** 1 **Gender:** F
Reported: 06/11/1998 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Required Visit to Doctor	Burning sensation in chest	
Coordination abnormal			
Gait disturbance	Required Visit to Doctor		
Nausea	Required Visit to Doctor		Stopped aropax

Medicine Details:

SEREPAX (Other drug) **Reason:**
Tablet 7.5 Milligram As necessary Oral
Batch: **Started:** 09/10/1998 **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/10/1998 **Stopped:** 16/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 132977 **Seq:** 1 **Gender:** F
Reported: 06/11/1998 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura	Required Specialist Consultation	Brusing over limbs and trunk	
Haemorrhage	Required Specialist Consultation	Increased bleeding also reported.	

Medicine Details:

RIVOTRIL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/06/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Possible past history bruising easily. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132979 **Seq:** 1 **Gender:** F
Reported: 06/11/1998 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Required Specialist Consultation	Auditory hallucinations	
Tinnitus	Required Specialist Consultation	Ringing in ears/like a radio playing songs in	Stopped aropax and changed to melleril.

Medicine Details:

TEMAZEPAM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 132980 **Seq:** 1 **Gender:** F
Reported: 06/11/1998 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 25/09/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne	Required Specialist Consultation	Whiteheads lumpy on forehead, back,	Stopped aropax
Diplopia	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 24/02/1997 **Stopped:** 11/09/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 132981 **Seq:** 1 **Gender:** F
Reported: 06/11/1998 **Weight:**
Hospitalisation: **Age:** 16
Onset Date: 12/10/1998 **DOB:** 18/09/1982
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haemoptysis	Required Specialist Consultation	Coughed up blood	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133007 **Seq:** 1 **Gender:** F
Reported: 02/12/1998 **Weight:** 60.00
Hospitalisation: **Age:** 36Y
Onset Date: 31/08/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Hyperhidrosis		Red itchy papules and sweating on legs	Aropax ceased and changed to zoloft. elocon treatment.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133203 **Seq:** 1 **Gender:** F
Reported: 16/11/1998 **Weight:** 50.00
Hospitalisation: **Age:** 45Y
Onset Date: 20/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Large ecchymoses on both thighs.	Ceased paroxetine.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Other drug) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 30/06/1998 **Stopped:** 15/10/1998

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 15/10/1998 **Stopped:** 21/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133234 **Seq:** 1 **Gender:** M
Reported: 16/11/1998 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 08/10/1997 **DOB:** 16/05/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Apathy Drug ineffective		Increased anger and irritability. Prominent negative symptoms.	Paroxetine was ceased

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

0.0

Batch: **Started:** 24/09/1997 **Stopped:** 08/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133351 **Seq:** 1 **Gender:** F
Reported: 19/11/1998 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: 19/04/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Asthenia		Lower limb spasm	Akineton prn and voltaren prn

Medicine Details:

AMLODIPINE (Other drug) **Reason:** Essential benign hypertension
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

RAMIPRIL (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

PRAVASTATIN SODIUM (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

FRUSEMIDE (Other drug) **Reason:**
20.0 Milligram Alternate days
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt has history of hypertention, cva right arm and leg weakness. choleapectomy diabetes - diet controlled

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133351 **Seq:** 1 **Gender:** F
Reported: 19/11/1998 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: 19/04/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

SLOW-K (Other drug)		**Reason:**	
	0.0	Alternate days	
Batch:	**Started:**	**Stopped:**	CONTIN
AROPAX (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**	**Stopped:**	

Laboratory Investigations:

Additional Information:

Pt has history of hypertention, cva right arm and leg weakness. choleapectomy diabetes - diet controlled

Report Detail

Case Number: 133389 **Seq:** 1 **Gender:** F
Reported: 18/11/1998 **Weight:**
Hospitalisation: **Age:** 41Y
Onset Date: 31/12/1996 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration			

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 14/08/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergies : penicillin-rash, aspirin-nausea, digesic-weak at knees, ees-vomit- ing, tenormin- nausea, warfarin-nausea. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Report Detail

Case Number: 133390 **Seq:** 1 **Gender:** F
Reported: 18/11/1998 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 18/06/1957
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Constipation	Severe	Severe constipation for 2 months	Dose of aropax gradually reduced then ceased.

Medicine Details:

DUPHALAC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:**
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/03/1998 **Stopped:** 28/06/1998

AROPAX (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 20/11/1997 **Stopped:** 01/06/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133392 **Seq:** 1 **Gender:** F
Reported: 18/11/1998 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 25/09/1950
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Headache Rash Weight increased		Body aches	Stopped aropax gradually.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133678 **Seq:** 1 **Gender:** M
Reported: 25/11/1998 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 23/10/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nervousness	Required Visit to Doctor	Emotionally irritable	
Disturbance in attention	Required Visit to Doctor	Fogginess or veil over head feeling.	
Insomnia	Required Visit to Doctor	Moderate difficulty in sleeping	Stopped aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 23/10/1998 **Stopped:** 03/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 133694 **Seq:** 1
Reported: 25/11/1998
Hospitalisation: Treated in outpatient department only.
Onset Date:
Outcome: Unknown

Gender: F
Weight: 70.00
Age: 44
DOB: 01/12/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Drug withdrawal syndrome			Valium. plan to reduced from 20mg to 10mg daily for 4 weeks then 5mg daily for 4 weeks, then cease

Medicine Details:

PROVELLE-28 (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/1996 **Stopped:** 28/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on aropax 20mg daily for 3-4 years, reduced dose to 10mg daily for one week, then 10mg on alternate nights for 1 week. towards end of second week patient experienced symptoms. was restarted on aropax 10mg. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133697 **Seq:** 1
Reported: 25/11/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 36Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium	Required Visit to Doctor	Delirious symptoms	Ceased aropax.

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug) **Reason:** Unspecified psychosis

Injection	20.0	Milligram	Weekly	Intravenous

Batch: **Started:** **Stopped:**

METHADONE HYDROCHLORIDE (Other drug) **Reason:**

Oral Liquid	40.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression

Tablet	0.0			Oral

Batch: **Started:** **Stopped:** 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133715 **Seq:** 1 **Gender:** M
Reported: 25/11/1998 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 14/04/1968
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

BENZTROPINE MESYLATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

DIAZEPAM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 650.0 Milligram Daily Oral
Batch: **Started:** 14/11/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 133799 **Seq:** 1
Reported: 30/11/1998
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 65Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Required Visit to Doctor		
Nausea	Required Visit to Doctor		
Syncope			

Medicine Details:

LIPEX (Other drug)			**Reason:**		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	
AROPAX (Suspected)			**Reason:**	Depression	
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
PLENDIL ER (Suspected)			**Reason:**		
	5.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133801 **Seq:** 1 **Gender:** F
Reported: 30/11/1998 **Weight:** 90.00
Hospitalisation: **Age:** 75
Onset Date: **DOB:** 22/05/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura	Severe	Bruising which lasted 10 days.	Ceased aropax.

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 21/04/1998 **Stopped:** 05/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Detail

Case Number: 133802 **Seq:** 1 **Gender:** F
Reported: 30/11/1998 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 06/06/1956
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Feeling bizarre	
Polyuria		Increased urinary output.	
Coordination abnormal		Lack of balance	
Depression			
Drug withdrawal syndrome			
Hypoaesthesia			
Sensory disturbance			

Medicine Details:

RIVOTRIL (Other drug) **Reason:**
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient slowly attempted to come off aropax, took 1/2 tablet for three days and experienced symptoms. is continuing on 1/2 tab daily.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 133966 **Seq:** 1 **Gender:** F
Reported: 03/12/1998 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			Paroxetine ceased

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

0.0

Batch: **Started:** 01/08/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to penicillin. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 134042 **Seq:** 1 **Gender:** M
Reported: 07/12/1998 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 29/03/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Medication ceased

Medicine Details:

NORVASC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
35.0 Dose Unspecified Weekly
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		04/07/1997	47	
	ALT = SGPT		27/11/1997	56	
	ALT = SGPT		09/06/1998	76	
	ALT = SGPT		10/09/1998	94	
	ALT = SGPT		16/07/1998	78	
	AST = SGOT		04/07/1997	34	
	AST = SGOT		27/11/1997	35	

Additional Information:

There has been no obvious physical symptoms associated with these changes.

Report Detail

Case Number: 134042 **Seq:** 1 **Gender:** M
Reported: 07/12/1998 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 29/03/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

NORVASC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
35.0 Dose Unspecified Weekly
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		09/06/1998	37	
	AST = SGOT		16/07/1998	48	
	AST = SGOT		10/09/1998	56	
	Albumin		04/07/1997	46	
	Albumin		27/11/1997	47	
	Albumin		09/06/1998	43	
	GGT = SGGT =		04/07/1997	21	

Additional Information:

There has been no obvious physical symptoms associated with these changes.

Report Detail

Case Number: 134042 **Seq:** 1 **Gender:** M
Reported: 07/12/1998 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 29/03/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

NORVASC (Other drug)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**
PAROXETINE HYDROCHLORIDE (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**
ALCOHOL (Suspected)		**Reason:**
	35.0 Dose Unspecified Weekly	
Batch:	**Started:**	**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =		27/11/1997	32	
	GGT = SGGT =		09/06/1998	43	
	GGT = SGGT =		16/07/1998	35	
	Glycosylated		04/07/1997	29	
	Glycosylated		27/11/1997	29	
	Glycosylated		09/06/1998	29	
	Protein		04/07/1997	75	

Additional Information:

There has been no obvious physical symptoms associated with these changes.

Report Detail

Case Number: 134042 **Seq:** 1 **Gender:** M
Reported: 07/12/1998 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 29/03/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

NORVASC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
35.0 Dose Unspecified Weekly
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Protein		27/11/1997	76	
	Protein		09/06/1998	72	
	Protein		16/07/1998	72	
	SAP = ALP		04/07/1997	76	
	SAP = ALP		27/11/1997	73	
	SAP = ALP		09/06/1998	74	
	SAP = ALP		16/07/1998	72	

Additional Information:

There has been no obvious physical symptoms associated with these changes.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134046 **Seq:** 1 **Gender:** F
Reported: 07/12/1998 **Weight:**
Hospitalisation: **Age:** 63Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy		Feels "dopy". "cant be bothered" feeling	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134047 **Seq:** 1 **Gender:** F
Reported: 07/12/1998 **Weight:** 54.00
Hospitalisation: **Age:** 28Y
Onset Date: 19/11/1998 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Swollen hands 3 days after starting aropax	Aropax ceased

Medicine Details:

DIANE-35 ED (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 01/04/1998 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 16/11/1998 **Stopped:** 19/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's hands swelled 3 days after starting aropax (20mg). aropax ceased and swelling decreased over 2 days. then restarted aropax 7 days later and swelling recurred. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 134053 **Seq:** 1 **Gender:** M
Reported: 07/12/1998 **Weight:** 75.00
Hospitalisation: **Age:** 59
Onset Date: **DOB:** 31/08/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Experiencing an inability to ejaculate	
Libido decreased		Loss of libido	Therapy stopped abruptly

Medicine Details:

PREDSOL (Other drug) **Reason:**
Suppository 20.0 Milligram As necessary Rectal
Batch: **Started:** L TERM **Stopped:**

AURORIX (Other drug) **Reason:**
300.0 Milligram Daily
Batch: **Started:** 10/11/1998 **Stopped:** CONTIN

ASPIRIN (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** 24/09/1998 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 27/09/1998 **Stopped:** 09/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

First episode of anxiety/depression disorder diagnosed in late september 98. past medical history of alcohol abuse; however not drinking since august.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134313 **Seq:** 1 **Gender:** M
Reported: 16/11/1998 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: **DOB:** 03/02/1966
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			Aropax ceased

Medicine Details:

ALCOHOL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 25/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was taking aropax approx. 6-9mths ago and immediately developed delay in ejaculation. he restarted aropax approx. 1wk ago and within first day noticed delayed ejaculation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134317 **Seq:** 1 **Gender:** F
Reported: 16/12/1998 **Weight:** 57.00
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 07/03/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Muscle twitching	Required Specialist Consultation	Generalised tremor all over body	Therapy continued unchanged

Medicine Details:

LEVLEN ED (Other drug) **Reason:**
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134320 **Seq:** 1 **Gender:** F
Reported: 16/12/1998 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 17/08/1948
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms	Required Visit to Doctor	Cramps --> limbs, feet, hands	
Malaise	Severe	Severe unwell feeling	
Drug withdrawal syndrome	Required Visit to Doctor		
Paresis	Required Visit to Doctor		
Sleep disorder			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 05/10/1998 **Stopped:** 15/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms are due to discontinuation of aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134322 **Seq:** 1 **Gender:** M
Reported: 16/12/1998 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Fatigue		Felt hyperactive	Therapy continued unchanged

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Oral application 20.0 Milligram Daily Oral
Batch: **Started:** 28/09/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt on aropax for 6 weeks. for 1st 4 weeks felt hyperactive. now feels lethargic and phisically down.

Report Detail

Case Number: 134448 **Seq:** 1 **Gender:** F
Reported: 21/12/1998 **Weight:** 48.00
Hospitalisation: **Age:** 34Y
Onset Date: 06/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Patient with congenital spasticity.	

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 01/01/1989 **Stopped:**

BACLOFEN (Other drug) **Reason:** Abnormal involuntary movement
6.0 Dose Unspecified Daily
Batch: **Started:** 01/01/1989 **Stopped:**

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Intensification of spaciticty in left arm 10 days after starting aropax. left arm is only usable limb. nil known reaction, no previous exposure. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Detail

Case Number: 134466 **Seq:** 1 **Gender:** F
Reported: 21/12/1998 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 03/02/1961
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Required Visit to Doctor	Inability to urinate	Aropax tapered quickly.

Medicine Details:

BREVINOR-1 (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 26/08/1998 **Stopped:** 08/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134468 **Seq:** 1 **Gender:** F
Reported: 21/12/1998 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: **DOB:** 26/09/1972
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/09/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134551 **Seq:** 1 **Gender:** F
Reported: 21/12/1998 **Weight:** 49.00
Hospitalisation: **Age:** 22
Onset Date: 21/07/1998 **DOB:** 02/06/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Asthenia Back pain Headache Hypertonia Nausea	 Severe	Neck stiffness.	 Midazolam iv 3 doses 2.5mg/2.5mg/2mg over 5hrs. cyproheptadine 4mg po prn (given 5 doses over 5 days). acyclovir 500mg q8h iv x 4 doses. ceftriazone 1gm iv daily x 1/7. panadeine forte 1-2 q4th prn. metoclopramide 10mg tds

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/08/1997 **Stopped:** 20/07/1998

NEFAZODONE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 21/07/1998 **Stopped:** 22/07/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134551 **Seq:** 1 **Gender:** F
Reported: 21/12/1998 **Weight:** 49.00
Hospitalisation: **Age:** 22
Onset Date: 21/07/1998 **DOB:** 02/06/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photophobia Serotonin syndrome Tremor Visual disturbance Vomiting			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/08/1997 **Stopped:** 20/07/1998

NEFAZODONE HYDROCHLORIDE (Interaction) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 21/07/1998 **Stopped:** 22/07/1998

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134584 **Seq:** 1 **Gender:** F
Reported: 24/12/1998 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination Amnesia Convulsion Headache Nausea Tremor		Visual auditory hallucinations	Ceased aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 01/06/1998 **Stopped:** 28/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134716 **Seq:** 1 **Gender:** M
Reported: 04/01/1999 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity			

Medicine Details:

AURORIX (Suspected) **Reason:** Depression
Tablet 300.0 Milligram 1 time Oral
Batch: **Started:** 27/12/1998 **Stopped:** 27/12/1998

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 18/11/1998 **Stopped:** 26/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt suffered symptoms half hour after taking first tab of aurorix. known allergy to coconut, peanut and penicillin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134718 **Seq:** 1
Reported: 04/01/1999
Hospitalisation: Admitted to hospital
Onset Date: 17/12/1998
Outcome: Recovered

Gender: M
Weight:
Age: 36Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal failure acute Hypotension Shock Syncope		Acute ranal impairment secondary to	Inotrope support, icu admission

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Oral application 10.0 Milligram Daily Oral

Batch: **Started:** 01/09/1998 **Stopped:** 17/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134760 **Seq:** 1 **Gender:** M
Reported: 04/01/1999 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 31/10/1998 **DOB:** 29/12/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure	Required Visit to Doctor		Aropax continued

Medicine Details:

COVERSYL (Other drug) **Reason:**
Oral application 4.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LASIX (Other drug) **Reason:**
Oral application 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CARVEDILOL HYDROCHLORIDE (Other drug) **Reason:**
Oral application 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/04/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134765 **Seq:** 1 **Gender:** M
Reported: 04/01/1999 **Weight:** 72.00
Hospitalisation: **Age:** 67Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Required Specialist Consultation		
Ejaculation failure	Required Specialist Consultation		Therapy unchanged
Weight increased	Required Specialist Consultation		

Medicine Details:

OROXINE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

RIVOTRIL (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

BETAMIN (Other drug) **Reason:** Unspec vitamin deficien states
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 01/08/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 134910 **Seq:** 1 **Gender:** F
Reported: 16/03/1999 **Weight:** 63.00
Hospitalisation: **Age:** 45Y
Onset Date: 31/01/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135059 **Seq:** 1 **Gender:** M
Reported: 11/01/1999 **Weight:**
Hospitalisation: **Age:** 21Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Tachycardia Agitation Anxiety Cold sweat Hyperreflexia Serotonin syndrome		Fine tremor Heart rate 110-120 bpm.	Cyproheptadine 8mg and then 4mg eight hourly.

Medicine Details:

DESIPRAMINE HYDROCHLORIDE (Interaction) **Reason:**

0.0

Batch: **Started:** **Stopped:** 5D

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:**

Tablet 1.0 Dose Unspecified 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135060 **Seq:** 1 **Gender:** F
Reported: 11/01/1999 **Weight:**
Hospitalisation: **Age:** 21Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Tachycardia Agitation Anxiety Dizziness Sensory disturbance Serotonin syndrome Tremor Vomiting		Electric shock sensation in arms and legs. Heart rate of 98 bpm.	Cyproheptadine 8mg and than 4mg eight hourly for 24 hrs.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
0.0
Batch: **Started:** L TERM **Stopped:**

VENLAFAXINE HYDROCHLORIDE (Interaction) **Reason:** Depression
37.5 Milligram Daily
Batch: **Started:** **Stopped:** 5D

VENLAFAXINE HYDROCHLORIDE (Interaction) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** **Stopped:** 2D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135095 **Seq:** 1
Reported: 14/01/1999
Hospitalisation:
Onset Date: 15/10/1998
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 13Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia		Worsening of a bald spot on top of head.	

Medicine Details:

DEXAMPHETAMINE SULPHATE (Suspected) **Reason:** Behavior disorders of childhod
3.0 Dose Unspecified Daily
Batch: **Started:** 01/09/1998 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 11/06/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135101 **Seq:** 1 **Gender:** F
Reported: 14/01/1999 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 20/01/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Micturition disorder Urinary incontinence			Ceased aropax

Medicine Details:

SURMONTIL (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 21/10/1997 **Stopped:** 09/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135213 **Seq:** 1 **Gender:** F
Reported: 18/01/1999 **Weight:**
Hospitalisation: **Age:** 80
Onset Date: **DOB:** 25/09/1918
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Severe	"horses outside of window"	Aropax ceased

Medicine Details:

LOSEC (Other drug) **Reason:** Other diseases of esophagus

Capsule 1.0 Dose Unspecified Daily Oral

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 1W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135218 **Seq:** 1 **Gender:** F
Reported: 18/01/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Required Specialist Consultation	Feels that aropax making parkinson	

Medicine Details:

SINEMET (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135222 **Seq:** 1 **Gender:** F
Reported: 18/01/1999 **Weight:**
Hospitalisation: **Age:** 17Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia	Required Specialist Consultation	Restless leg symptoms occur when sitting	

Medicine Details:

NORDETTE NOS (Other drug) **Reason:** Contraception
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135223 **Seq:** 1 **Gender:** M
Reported: 18/01/1999 **Weight:**
Hospitalisation: **Age:** 70
Onset Date: **DOB:** 05/08/1928
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Specialist Consultation	Itchy skin, occasional sweating	
Sexual dysfunction	Required Specialist Consultation	Sex problems	
Vertigo		To the point where patient is falling over.	
Dry mouth	Required Specialist Consultation		Drug ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** 08/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135340 **Seq:** 1 **Gender:** F
Reported: 22/01/1999 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 03/04/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Night sweats in the last few months.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135348 **Seq:** 1 **Gender:** M
Reported: 27/01/1999 **Weight:** 92.00
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 26/09/1962
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Required Specialist Consultation	Always sleepy, but can't sleep	
Somnolence	Required Specialist Consultation	Feeling drowsy	Therapy stopped abruptly.
Anxiety	Required Specialist Consultation	Feeling more anxious increased panic	
Suicide attempt	Required Specialist Consultation	Suicidal thoughts	

Medicine Details:

THIAMINE (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

VITAMIN B COMPLEX (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 18/12/1998 **Stopped:** 01/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax increased to 30mg/day on 24/12/98. treatment restarted and appears to be side effect free. patient has history of contact allergies/urticarial reactions.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135349 **Seq:** 1 **Gender:** M
Reported: 27/01/1999 **Weight:** 75.00
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 03/12/1945
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure	Severe	Impossible ejaculation most times	Dose tapered gradually: 10mg for 3 days, 5mg for 4 days, stop
Ejaculation failure	Severe		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 2M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Problem resolved on cessation of treatment.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135429 **Seq:** 1 **Gender:** M
Reported: 29/01/1999 **Weight:** 83.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Accommodation disorder		Blurred vision	

Medicine Details:

IMIGRAN (Suspected) **Reason:**
Spray 0.0 As necessary Nasal
Batch: **Started:** **Stopped:** CONTIN

PREPULSID FORTE (Suspected) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** 01/04/1998 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 01/04/1998 **Stopped:** CONTIN

XANAX (Suspected) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 01/05/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 135429 **Seq:** 1 **Gender:** M
Reported: 29/01/1999 **Weight:** 83.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

LOSEC (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 01/05/1998 **Stopped:** CONTIN

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135735 **Seq:** 1 **Gender:** M
Reported: 01/02/1999 **Weight:** 35.00
Hospitalisation: **Age:** 14Y
Onset Date: 21/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension Dizziness Tachycardia		87/51	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135744 **Seq:** 1 **Gender:** M
Reported: 03/02/1999 **Weight:** 90.00
Hospitalisation: **Age:** 60Y
Onset Date: 07/12/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema	Severe	Severe swelling of lip	Aropax discontinued.

Medicine Details:

FELDENE (Other drug) **Reason:**
10.0 Milligram As necessary
Batch: **Started:** 01/05/1998 **Stopped:** 28/06/1998

AROPAX (Suspected) **Reason:**
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 4D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135757 **Seq:** 1 **Gender:** U
Reported: 02/02/1999 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: **DOB:** 02/03/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 135764 **Seq:** 1 **Gender:** F
Reported: 04/02/1999 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 07/01/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myo-clonus jerks.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 16/11/1998 **Stopped:** 18/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135777 **Seq:** 1 **Gender:** F
Reported: 04/02/1999 **Weight:** 88.00
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Vasculitis		Rash on legs, arms, face.	Prednisone.

Medicine Details:

DEPO-PROVERA (Other drug) **Reason:**
150.0 Milligram 1 time
Batch: **Started:** 01/01/1997 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 02/02/1998 **Stopped:** 01/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 135788 **Seq:** 1 **Gender:** F
Reported: 04/02/1999 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Tinnitus Vertigo			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/01/1995 **Stopped:** 28/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt experienced symptoms immediately after stopping paroxetine abruptly. recommenced drug and tapered dose down to 10mg-> 5mg -> 2.5 mg-> till stopped. still has symptoms. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Report Detail

Case Number: 135838 **Seq:** 1 **Gender:** F
Reported: 05/02/1999 **Weight:** 76.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		To 89kg over 1 year, originally 65-70kg	

Medicine Details:

ZOCOR (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 12/06/1997 **Stopped:** 10/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After 2.5 months off aropax, weight dropped to 76kg. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136098 **Seq:** 1
Reported: 11/02/1999
Hospitalisation:
Onset Date: 03/02/1999
Outcome: Not yet recovered

Gender: F
Weight: 49.00
Age: 40Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia Abdominal pain Diarrhoea Nausea Tremor Vomiting		Hot and cold.	

Medicine Details:

LAMICTAL (Other drug) **Reason:** Other&unspecified epilepsy
100.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

EPILIM (Other drug) **Reason:** Other&unspecified epilepsy
1.0 Gram Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** 01/02/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms two days after starting aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136271 **Seq:** 1 **Gender:** F
Reported: 17/02/1999 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 25/10/1945
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura	Required Specialist Consultation	Bruising	
Rash	Required Specialist Consultation	Itchy rash	Therapy stopped abruptly
Insomnia	Required Specialist Consultation	Lack of sleep	
Hyperhidrosis	Required Specialist Consultation	Sweatiness	

Medicine Details:

VALIUM (Other drug) **Reason:**
Tablet 5.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

PREMARIN (Other drug) **Reason:**
Tablet 1.2 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PROVERA (Other drug) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SALAZOPYRIN (Other drug) **Reason:**
Tablet 2.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136271 **Seq:** 1 **Gender:** F
Reported: 17/02/1999 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: **DOB:** 25/10/1945
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia	Required Specialist Consultation		
Dyspnoea	Required Specialist Consultation		
Tremor	Required Specialist Consultation		

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:**

Tablet	200.0	Microgram	Daily	Oral

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression

Tablet	20.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 1M

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136307 **Seq:** 1 **Gender:** F
Reported: 16/02/1999 **Weight:** 60.00
Hospitalisation: **Age:** 40Y
Onset Date: 09/02/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Aches	
Diarrhoea			
Drug withdrawal syndrome			
Fatigue			
Nausea			Stopped aropax 20mg 5 days ago and suffered symptoms. re-start aropax 20mg daily.
Nervousness			

Medicine Details:

BREVINOR (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 27/10/1997 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 19/09/1997 **Stopped:** 06/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136359 **Seq:** 1
Reported: 19/02/1999
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 84.00
Age: 58Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fixed eruption Pruritus		Fixed drug rash, both arms --> raised red	

Medicine Details:

XANAX (Suspected)		**Reason:** Depression		
Tablet	1.5 Milligram	As necessary	Oral	
Batch:	**Started:** 01/12/1997		**Stopped:**	CONTIN
AROPAX (Suspected)		**Reason:** Depression		
Tablet	20.0 Milligram	Daily	Oral	
Batch:	**Started:** 17/11/1998		**Stopped:**	09/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient improving. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136395 **Seq:** 1
Reported: 19/02/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 67.00
Age: 80Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

ASPIRIN (Suspected) **Reason:** Acute,ill-def cerebrovascular disease w/o hyperte
100.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:** CONTIN

ATENOLOL (Suspected) **Reason:** Essential benign hypertension
50.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		18/01/1999	128	
	Sodium		20/01/1999	127	
	Sodium		21/01/1999	128	
	Sodium		22/01/1999	128	
	Sodium		23/01/1999	132	
	Sodium		24/01/1999	131	
	Sodium		25/01/1999	129	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136395 **Seq:** 1
Reported: 19/02/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 67.00
Age: 80Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ASPIRIN (Suspected)			**Reason:**	Acute,ill-def cerebrovascular disease w/o hyperte
	100.0 Milligram	Daily		
Batch:	**Started:** 01/01/1999		**Stopped:**	CONTIN
ATENOLOL (Suspected)			**Reason:**	Essential benign hypertension
	50.0 Milligram	Daily		
Batch:	**Started:**		**Stopped:**	CONTIN
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression
	20.0 Milligram	Daily		
Batch:	**Started:** 01/01/1999		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		27/01/1999	134	
	Sodium		01/02/1999	138	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136526 **Seq:** 1 **Gender:** F
Reported: 22/02/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia	Severe		Dose tapered gradually

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** 12M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bone marrow Platelets				Normal red blood cell and white blood cell lineages. dysplastic locking megakaryocytes consistent with poisoning or dysplasia. Platelet count of 40

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136527 **Seq:** 1 **Gender:** M
Reported: 22/02/1999 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Required Visit to Doctor	Disorientated	
Dizziness	Required Visit to Doctor	Felt extremely dizzy	
Drug withdrawal syndrome	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 01/03/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Trying to wean off aropax. patient takes 10mg one day and then 20mg the next, (alternate dosing). missed a dose of 20mg one day - reactions. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136608 **Seq:** 1 **Gender:** F
Reported: 25/02/1999 **Weight:** 68.00
Hospitalisation: **Age:** 55Y
Onset Date: 03/01/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Tingling sensation to facial skin across	

Medicine Details:

TAZAC (Other drug) **Reason:** Abdominal pain
300.0 Milligram Daily
Batch: **Started:** 08/12/1998 **Stopped:**

PRAVACHOL (Other drug) **Reason:** Othr&unspec metabolic diseases
10.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 04/12/1998 **Stopped:** 20/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient previously had 20mg/day. problem seemed to occur with doubling dose. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136610 **Seq:** 1
Reported: 24/02/1999
Hospitalisation:
Onset Date: 15/02/1999
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 48Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Giddiness/dizziness esp if turns head	Aropax 20mg daily, then 10mg/d for 5 days, then 10mg 2nd daily for 7 days, then 5 days later still has some dizziness

Medicine Details:

LANOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
250.0 Microgram Daily
Batch: **Started:** 01/08/1998 **Stopped:** CONTIN

ASPIRIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
150.0 Milligram Daily
Batch: **Started:** 01/08/1998 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Reducing Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136926 **Seq:** 1 **Gender:** M
Reported: 04/03/1999 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis		Blood clot	
Myalgia		Muscular aches and pains	Ceased aropax
Hypertonia	Severe		
Muscle spasms	Severe		

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 136964 **Seq:** 0
Reported: 08/03/1999
Hospitalisation: Admitted to hospital
Onset Date: 14/11/1998
Outcome: Unknown

Gender: F
Weight:
Age: 77Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerks.	Treated with epilim.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 03/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt rechallenged on paroxetine with recurrence of symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137099 **Seq:** 1
Reported: 09/03/1999
Hospitalisation: Admitted to hospital
Onset Date: 16/12/1998
Outcome: Recovered

Gender: M
Weight:
Age: 36Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperventilation			
Hypotension			
Neuroleptic malignant syndrome			
Pyrexia			
Syncope			
Tachycardia			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 01/10/1998 **Stopped:** 16/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Underlying long standing neurological deficits - has cerebal palsy. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137113 **Seq:** 1 **Gender:** F
Reported: 09/03/1999 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia	Required Visit to Doctor	Excessive bleeding during period.	

Medicine Details:

OROXINE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Thyroid abnormality may have been responsible for the heavy bleeding. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137114 **Seq:** 1 **Gender:** M
Reported: 09/03/1999 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 14/03/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Reducing Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt only experienced symptoms on 20mg dose of aropax not occurring on 10mg dose

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137132 **Seq:** 1
Reported: 09/03/1999
Hospitalisation:
Onset Date: 01/03/1999
Outcome: Not yet recovered

Gender: F
Weight: 52.00
Age: 37Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Dizziness Drug withdrawal syndrome Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/12/1998 **Stopped:** 26/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt experienced symptoms 2 days after stopping aropax. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137199 **Seq:** 1 **Gender:** M
Reported: 11/03/1999 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 31/03/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Dehydration Depression Nervousness		Myoclonic jerks	Paroxetine to be withdrawn.

Medicine Details:

DIGOXIN (Other drug) **Reason:** Congestive heart failure
Tablet 62.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** 28/02/1999

FRUSEMIDE (Other drug) **Reason:** Congestive heart failure
Oral application 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

CAPTOPRIL (Other drug) **Reason:** Congestive heart failure
Tablet 37.5 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

TEMAZEPAM (Other drug) **Reason:**
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** 01/03/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has declining renal function and recent declinging k+ (still on normal range) - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 137199 **Seq:** 1 **Gender:** M
Reported: 11/03/1999 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 31/03/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

FAMOTIDINE (Other drug)			**Reason:**	Hernia of unspecified site	
Tablet	40.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
ASPIRIN (Other drug)			**Reason:**		
Oral application	150.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Tablet	40.0	Milligram	Daily		Oral
Batch:	**Started:**	01/02/1999		**Stopped:**	

Laboratory Investigations:

Additional Information:

Has declining renal function and recent declinging k+ (still on normal range) - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137210 **Seq:** 1 **Gender:** M
Reported: 11/03/1999 **Weight:** 90.00
Hospitalisation: **Age:** 30Y
Onset Date: 05/03/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/02/1999 **Stopped:** 04/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt developed feeling of "jolts, whoozes, buzzes, pulses" throuh body/limbs and face over 10-20 secs. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137370 **Seq:** 1
Reported: 16/03/1999
Hospitalisation:
Onset Date: 31/12/1998
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 42Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Restless feeling - mainly legs	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/11/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137502 **Seq:** 1 **Gender:** M
Reported: 18/03/1999 **Weight:** 75.00
Hospitalisation: **Age:** 37Y
Onset Date: 31/01/1997 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			Ceased aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** 28/09/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Increased sweating has persisted since stopping drug. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137554 **Seq:** 1 **Gender:** M
Reported: 19/03/1999 **Weight:** 70.00
Hospitalisation: **Age:** 70Y
Onset Date: 25/02/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 25/02/1999 **Stopped:** 28/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Please see original report for details of other drugs - norvasc, coversyl, aldomet.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137607 **Seq:** 1 **Gender:** M
Reported: 19/03/1999 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 31/12/1998 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction		Abnormal ejaculation.	

Medicine Details:

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137688 **Seq:** 1 **Gender:** F
Reported: 23/03/1999 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: **DOB:** 25/04/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aphasia		Expressive dysphasia after 8 hours.	
Nausea		Nausea within one hour after first dose.	
Tremor		Tremor within one hour after first dose.	Aropax discontinued.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 03/03/1999 **Stopped:** 04/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had expressive dysphasia (she could find words but could not express them) the problem gradually resolved itself and the patient was almost back to normal 24hrs after dose. see original report for other drugs - ceclor, tilade, vitamin, & roxithromycin past history of asthma.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137710 **Seq:** 1 **Gender:** F
Reported: 23/03/1999 **Weight:** 65.00
Hospitalisation: **Age:** 20Y
Onset Date: 15/03/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 137968 **Seq:** 1 **Gender:** M
Reported: 30/03/1999 **Weight:** 94.00
Hospitalisation: **Age:** 19Y
Onset Date: 12/03/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Panic secondary to symptoms	
Headache	Severe	Sensation of head rush then severe headache	Penicillin 8mg prn (up to 32mg/day) for 4 days then 16mg/day for 2-3 days + codeine phosphate imi when pethidine failed imi
Hypertonia			
Hyperventilation			
Paraesthesia			

Medicine Details:

ANAFRANIL (Suspected) **Reason:**
50.0 Milligram 1 time
Batch: **Started:** 11/03/1999 **Stopped:** 12/03/1999

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram As necessary Oral
Batch: **Started:** 25/02/1999 **Stopped:** 04/03/1999

LUMIN (Suspected) **Reason:** Specific disorders of sleep
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 06/11/1998 **Stopped:** 12/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions not reversed by rebreathing. suspected drugs given for severe ptsd. see original report for details of other drugs - neulactil, mogadon, normison.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138097 **Seq:** 1 **Gender:** F
Reported: 01/04/1999 **Weight:** 62.00
Hospitalisation: **Age:** 19Y
Onset Date: 10/12/1997 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Coordination abnormal Tetany Yawning		Lack of hand and mouth coordination.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 10/12/1997 **Stopped:** 26/10/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Drug stopped and then continued on 03/01/99 and symptoms returned for the first 3 weeks. see original report for details of other drugs.- triphasil 28, ventolin mda.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138111 **Seq:** 1 **Gender:** M
Reported: 12/04/1999 **Weight:** 120.00
Hospitalisation: **Age:** 28Y
Onset Date: 01/04/1999 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Vomiting			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/04/1999 **Stopped:** 07/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Drug ceased ror 1 week & retried causing same symptoms. see original report for details of other drugs.-pulmicort 400, feldene 20 and salazopyrin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138199 **Seq:** 1 **Gender:** F
Reported: 09/04/1999 **Weight:** 56.00
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 07/12/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching	Severe	Severe muscle and joint twitching	Dose of aropax reduced to 10mg then ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138200 **Seq:** 1 **Gender:** F
Reported: 09/04/1999 **Weight:**
Hospitalisation: **Age:** 67
Onset Date: 31/12/1996 **DOB:** 16/09/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Severe	Severe sweating	Dose of aropax tapered gradually over one week.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs: thyroxine and orudis. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138201 **Seq:** 1 **Gender:** M
Reported: 09/04/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Visit to Doctor	Hot skin across chest and back of neck.	Ceased aropax
Dizziness	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Tremor	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 202.0 Milligram Daily Oral
Batch: **Started:** 11/02/1999 **Stopped:** 11/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had a similar experience with zoloft in the past. please see original report for details of other drug - diazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138211 **Seq:** 1 **Gender:** F
Reported: 01/04/1999 **Weight:** 54.00
Hospitalisation: **Age:** 27Y
Onset Date: 19/03/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Explosive diarrhoea for 9 days	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 17/03/1999 **Stopped:** 26/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to sulphonamides. see original report for details of other drugs - trifeme, becloforte.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138225 **Seq:** 1 **Gender:** F
Reported: 01/04/1999 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 05/07/1977
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Menstrual bleeding has completely ceased.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/08/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - ventolin & becotide. no prior history of menstrual irregularities. missed the 2 subsequent periods. periods then restarted and remain regular.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138499 **Seq:** 1 **Gender:** M
Reported: 19/04/1999 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Tinnitus		When aropax reduced to less than 20mg	Serc, stemitil

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/01/1997 **Stopped:** 31/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138638 **Seq:** 1 **Gender:** M
Reported: 22/04/1999 **Weight:**
Hospitalisation: **Age:** 99U
Onset Date: 22/02/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia neonatal		Abnormal movements	
Respiratory disorder neonatal		High respiratory rate	
Fever neonatal		High temperature	
Agitation neonatal		Jitteriness	
Bradycardia		Low heart rate at delivery	
Neonatal disorder			

Medicine Details:

CEPHALEXIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

CANNABIS PREPARATION (Suspected) **Reason:**
5.0 Dose Unspecified Daily
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Abnormal movements, jitteriness, at delivery low heart rate, mother breast feeding, 24hrs post delivery respiratory rate high, high temperature. mother gestational diabetic undiagnosed - during delivery mother loss of consciousness (decreased bp) recovered. baby moderate to severe tremors, no increase in muscle tone, loose stools, not feeding well. Other drug - ascorbic acid.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138656 **Seq:** 1 **Gender:** F
Reported: 22/04/1999 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 31/01/1999 **DOB:** 16/11/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mastitis		Mastitis for a week.	
Galactorrhoea		Milk from breasts for a year	Cephalexin, decreased dose of paroxetine.
Amenorrhoea		Not menstruating for 2 years.	

Medicine Details:

HEROIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No known allergies. see original report for details of other drug - diazepam. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138844 **Seq:** 1 **Gender:** F
Reported: 28/04/1999 **Weight:** 65.00
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased	Severe	Severe loss of libido for days.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/03/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138895 **Seq:** 1 **Gender:** F
Reported: 29/04/1999 **Weight:** 69.00
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Dizziness Drug withdrawal syndrome		Extreme rage.	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 27/05/1998 **Stopped:** 12/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been taking 40mg for severe anxiety. the patient felt that they no longer needed it and slowly too themselves off (ie 20mg or 6 weeks and then 10mg for two months). pt is now back on 20mg/d still on. no allergies, no previous drug reactions. patient history: asthma, panic disorder.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 138898 **Seq:** 1 **Gender:** F
Reported: 29/04/1999 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Galactorrhoea lasted for days.	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - ativan. previous exposure to aropax in 1994. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139159 **Seq:** 1 **Gender:** F
Reported: 04/05/1999 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Fatigue Libido decreased Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 26/03/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax dose was incresed to 40mg daily on 17/04/99 but fatigue and loss of sexual feeling persisted. see original report for other drugs: premarin & provera.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139200 **Seq:** 1 **Gender:** F
Reported: 04/05/1999 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 01/09/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Erythema multiforme		Rash on legs, buttocks & lower abdomen.	Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/04/1998 **Stopped:** 26/03/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug detail - amprace, aspirin & quinate. rash took 3 weeks to clear after aropax ceased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139242 **Seq:** 1 **Gender:** F
Reported: 06/05/1999 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: 20/01/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthritis		Aching and swelling in wrists	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 19/12/1998 **Stopped:** 03/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139428 **Seq:** 1
Reported: 12/05/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 50.00
Age: 26Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Macular rash on trunk.	
Pyrexia		Temp of 38 degrees c.	
Abdominal pain			
Jaundice			Aropax ceased.
Pruritus			
Rash			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 10/03/1999 **Stopped:** 02/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT				Alt 181.
	AST = SGOT				Ast 362.
	Bilirubin				Tb 45.
	SAP = ALP				Alp 315.

Additional Information:

Allergy to bactrim - rash.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139570 **Seq:** 1 **Gender:** F
Reported: 12/05/1999 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue	Required Visit to Doctor	Heaviness in legs.	Patient abruptly stopped

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139571 **Seq:** 1 **Gender:** F
Reported: 10/05/1999 **Weight:** 60.00
Hospitalisation: **Age:** 76
Onset Date: **DOB:** 08/03/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Required Visit to Doctor	Lack of breath	Ceased aropax and changed to sertraline.
Abdominal pain	Required Visit to Doctor	Pain in bowel	
Diarrhoea	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Nausea	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 11/04/1999 **Stopped:** 13/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drugs: serepax, naprosyn. patient has irritable bowel syndrome.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139573 **Seq:** 1 **Gender:** F
Reported: 17/05/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia	Severe		Aropax stopped abruptly.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Extreme neck rigidity, with extreme difficulty moving her neck. past history of frequent back/neck pain. never similar episodes.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139715 **Seq:** 1
Reported: 21/05/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 105.00
Age: 13Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Polydipsia Polyuria			Ceased aropax and given insulin & metformin.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 22/04/1998 **Stopped:** 16/05/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139760 **Seq:** 1 **Gender:** F
Reported: 21/05/1999 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dystonia Muscle twitching Oculogyration Torticollis		Clenched jaw	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother took paroxetine first two weeks of pregnancy then ceased. recommenced at 4 months and continued till birth then ceased. started breastfeeding 6 days after birth, baby suffered torticollis, oculogyric crisis, dystonia (clenched jaw), twitching. baby was born 1/10/98.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139797 **Seq:** 1
Reported: 24/05/1999
Hospitalisation:
Onset Date: 13/04/1999
Outcome: Not yet recovered

Gender: F
Weight: 100.00
Age: 65Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pleural fibrosis Respiratory disorder			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

20.0 Milligram Daily

Batch: **Started:** 01/01/1995 **Stopped:** 04/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Moderately severe resricture ventilatory defect (fev, 78%) predicted. total lung capacity 64%. predicted).

Additional Information:

See origianl report for other drugs: isoptin, mixtard, lasix, slow-k. extensive pleural thickening not present on previous cxr's & ct's. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139802 **Seq:** 1 **Gender:** F
Reported: 24/05/1999 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 14/12/1973
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		" jittery."	
Fatigue		Tiredness (12-24 hours later)	
Affect lability			
Dizziness			
Headache			
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs. ventolin inhaler and voltaren emulgel.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139906 **Seq:** 1 **Gender:** F
Reported: 25/05/1999 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: 01/05/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Jaundice			

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:** 18/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		06/05/1999	201	
	ALT = SGPT		18/05/1999	44	
	Bilirubin		06/05/1999	49	
	Bilirubin		18/05/1999	12	
	GGT = SGGT =		06/05/1999	242	
	GGT = SGGT =		18/05/1999	111	
	SAP = ALP		06/05/1999	136	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139906 **Seq:** 1 **Gender:** F
Reported: 25/05/1999 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: 01/05/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:** 18/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		18/05/1999	91	

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139986 **Seq:** 1 **Gender:** F
Reported: 27/05/1999 **Weight:**
Hospitalisation: Treated in outpatient department only. **Age:** 74Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysphagia Pneumonia			

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139996 **Seq:** 1 **Gender:** M
Reported: 28/05/1999 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Pollakiuria			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/03/1999 **Stopped:** 22/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		21/04/1999	195	
	AST = SGOT		28/04/1999	159	
	AST = SGOT		06/05/1999	140	
	Albumin		21/04/1999	55	
	Albumin		28/04/1999	44	
	Albumin		06/05/1999	44	
	Biochemistry				Urobilinogen and protein (1+) found in the urine.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 139996 **Seq:** 1 **Gender:** M
Reported: 28/05/1999 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detai

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/03/1999 **Stopped:** 22/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Protein		21/04/1999	100	
	Protein		28/04/1999	88	
	Protein		06/05/1999	88	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140116 **Seq:** 1 **Gender:** F
Reported: 01/06/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Agitation Headache Drug withdrawal syndrome	Severe	Patient felt sick in the stomach. Patient was feeling agitated. Severe headache at top of head & above	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 14/02/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - minulet. patient has been on aropax for approximately 18 months and stopped taking tablets abruptly on 14.2.99.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140277 **Seq:** 1 **Gender:** F
Reported: 07/06/1999 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 24/11/1997 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Right sided headache	
Bradycardia		Sinus bradycardia	
Tremor		Tremulous	
Anorexia			
Diarrhoea			
Dry mouth			
Hyperhidrosis			
Insomnia			
Nocturia			
Polyuria			Drug ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 13/11/1997 **Stopped:** 27/11/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140295 **Seq:** 1 **Gender:** F
Reported: 07/06/1999 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Serious itching	Reduced dose
Nausea		Severe nausea	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred with increased dose of aropax from 20mg to 40 mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140296 **Seq:** 1 **Gender:** F
Reported: 07/06/1999 **Weight:** 64.00
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Feeling of unreality	
Anxiety		Quivering inside body	Diazepam
Depression		Tearfulness	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 04/11/1997 **Stopped:** 15/03/1999

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 15/03/1999 **Stopped:** 01/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drug therapy: triphasil.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140297 **Seq:** 1 **Gender:** M
Reported: 07/06/1999 **Weight:**
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Somnolence		Feeling tired and washed out.	Changed from morning dose to night dose of aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 20/05/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140322 **Seq:** 1 **Gender:** F
Reported: 08/06/1999 **Weight:** 85.00
Hospitalisation: **Age:** 49Y
Onset Date: 19/05/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal impairment		Liver induced renal fibrosis.	

Medicine Details:

LITHICARB (Suspected) **Reason:**
12.0 Gram Daily
Batch: **Started:** **Stopped:** 04/06/1999

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:** 04/06/1999

OGEN (Suspected) **Reason:** Menopausal symptoms
Tablet 1.2 Milligram Daily Oral
Batch: **Started:** 10/03/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drug- modecate.

Report Detail

Case Number: 140353 **Seq:** 1 **Gender:** F
Reported: 08/06/1999 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 22/04/1957
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea	Required Specialist Consultation		
Galactorrhoea	Required Specialist Consultation		
Menstrual disorder	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 18/02/1999 **Stopped:** CONTIN

AURORIX (Suspected) **Reason:** Depression
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/01/1999 **Stopped:** 18/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140354 **Seq:** 1 **Gender:** F
Reported: 08/06/1999 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching	Required Specialist Consultation	Occuring in all striated muscles but not the	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax dosage has been increased to 50mg/day with fasciculations still occuring though occasional and transient.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140356 **Seq:** 1 **Gender:** M
Reported: 08/06/1999 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 02/06/1951
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance	Required Specialist Consultation	Blurred vision for weeks	
Thirst		Increased thirst.	
Stomatitis		Sore mouth	
Agitation			
Confusional state			
Constipation			
Disturbance in attention			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

BUSPAR (Suspected) **Reason:** Anxiety neurosis
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: mogadon.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140414 **Seq:** 1 **Gender:** F
Reported: 10/06/1999 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 01/10/1958
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Diarrhoea Rash		" severe " panic attacks.	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Gi dis presum psychogenic orig

Tablet 20.0 Milligram 1 time Oral

Batch: **Started:** 11/05/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140645 **Seq:** 1 **Gender:** F
Reported: 18/06/1999 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: 10/06/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Palpitations			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 01/09/1998 **Stopped:** 28/06/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140784 **Seq:** 1 **Gender:** F
Reported: 22/06/1999 **Weight:**
Hospitalisation: **Age:** 63
Onset Date: 05/05/1999 **DOB:** 11/08/1935
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Hyperhidrosis		Cold and shivering	Symptoms alleviated when patient takes 2.5mg nitrazepam each night at approx. 7-8pm.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug: premarin.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140891 **Seq:** 1 **Gender:** F
Reported: 28/06/1999 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 10/06/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Patient experienced light headedness.	Sudaed ceased.
Chest pain		Pt experienced a burning sensation in the [illegible]	

Medicine Details:

SUDAFED (Interaction) **Reason:** Otr ecz&der due otr&unsp cause
0.0
Batch: **Started:** 10/06/1999 **Stopped:** 10/06/1999

AROPAX (Interaction) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 08/06/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140960 **Seq:** 1 **Gender:** M
Reported: 29/06/1999 **Weight:** 86.00
Hospitalisation: **Age:** 39Y
Onset Date: 31/12/1996 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms		Cramps esp. upper body and hands	Ceased aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1996 **Stopped:** 31/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 140967 **Seq:** 1 **Gender:** F
Reported: 29/06/1999 **Weight:**
Hospitalisation: **Age:** 12Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Somnolence			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occured after dose was increased to 20mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141319 **Seq:** 1 **Gender:** F
Reported: 09/07/1999 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 31/10/1998 **DOB:** 09/01/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Bruising	Aropax discontinued.
Dizziness		Feeling dizzy.	
Sexual dysfunction		Sexual dysfunction.	
Diarrhoea			
Drug withdrawal syndrome			
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 12/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After appropriate wash out period patient started on aurorix with incidence. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141320 **Seq:** 1 **Gender:** F
Reported: 09/07/1999 **Weight:** 66.00
Hospitalisation: **Age:** 63
Onset Date: **DOB:** 28/03/1936
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura Hyperhidrosis		Little bruises. Sweaty.	Aropax discontinued.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 16/11/1998 **Stopped:** 28/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs. - valium, tritace and lipex. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141321 **Seq:** 1 **Gender:** F
Reported: 09/07/1999 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 08/12/1951
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			Aropax discontinued.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 14/04/1999 **Stopped:** 14/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has been on aropax for 4 weeks.on 10mg/daily for 5 days, dose was increased to 20mg/daily. reaction occurred 10-14 days after treatment. also patient noticed increase in cigarette smoking (from 15 to 20) cigarettes a day.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141573 **Seq:** 1 **Gender:** F
Reported: 14/07/1999 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 20/02/1947
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Required Specialist Consultation	Became more noticable as time went on.	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tinnitus took 6 months to subside.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141575 **Seq:** 1 **Gender:** F
Reported: 14/07/1999 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 18/02/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Generalized twitching.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details of other drugs. - tegretol and lithium.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141576 **Seq:** 1 **Gender:** F
Reported: 14/07/1999 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 03/04/1961
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema			Therapy with aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Daily Oral
Batch: **Started:** 01/01/1999 **Stopped:** 01W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Angioneurotic oedema occurred after therapy with aropax. also occurred after therapy with efexor, aurorix, xanax and zoloft. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141577 **Seq:** 1 **Gender:** M
Reported: 14/07/1999 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Chest pain		Distressed - several panic attacks.	Diazepam 2 - 4 mg twice daily.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 5D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had tightness of tongue; difficulty in moving tongue.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141578 **Seq:** 1 **Gender:** F
Reported: 14/07/1999 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		"panicky" lasted 1/2 -1 hour	
Flushing		Skin flushed on cheeks and neck lasted	
Paraesthesia		Tingling sensation up the back lasted 1/2	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 23/06/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141658 **Seq:** 1
Reported: 16/07/1999
Hospitalisation: Treated in outpatient department only.
Onset Date: 01/07/1999
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 42Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia Paraesthesia		All over sensation of numbness. Left sided facial paraesthesia	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

10.0 Milligram Total

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking interferon.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141785 **Seq:** 1 **Gender:** F
Reported: 21/07/1999 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 09/04/1974
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching	Required Specialist Consultation	Twitching epigastric region	Therapy stopped abruptly

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 30/05/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred after second dose. patient was epileptic as a child; on no medication.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141942 **Seq:** 1 **Gender:** M
Reported: 26/07/1999 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 16/03/1999 **DOB:** 07/08/1972
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Required Visit to Doctor		
Drug withdrawal syndrome			
Nausea	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 15/03/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on aropax 20mg daily for approx. 18 months. when reduced to 10mg daily reaction occured. same reaction occured with susequent dose reductions. see original report for other drug details: panadeine forte.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 141943 **Seq:** 1 **Gender:** F
Reported: 26/07/1999 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Mania			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/02/1999 **Stopped:** 28/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient reported taking 120mg/day once during the therapy period but it is possible that higher than recommended doses were used more than once. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142018 **Seq:** 1 **Gender:** F
Reported: 28/07/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Dizziness Drug withdrawal syndrome Tremor	Required Visit to Doctor	Tingling in arms and legs	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on aropax for approx. 12 months and ceased over 1 month (1 week at each of the following doses 40mg -> 30mg -> 20mg -> 10mg) and reaction occured after ceasing.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142040 **Seq:** 1
Reported: 29/07/1999
Hospitalisation: Admitted to hospital
Onset Date: 07/12/1998
Outcome: Recovered

Gender: F
Weight:
Age: 89Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		Deterioration for 2 weeks - increased	High salt diet and fluids, iv normal saline and kcl. paroxetine ceased and other medications
Vomiting		Poor oral intake / vomiting	
Hypokalaemia			
Hyponatraemia			

Medicine Details:

MODURETIC (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 23/12/1998

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 23/12/1998

SINEQUAN (Suspected) **Reason:**
Capsule 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/12/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium		23/12/1998	2.5	
	Sodium		23/12/1998	108	

Additional Information:

See original report for details of other drugs - prednisone, senokot.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142254 **Seq:** 1 **Gender:** M
Reported: 02/08/1999 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 29/09/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Periorbital oedema		Eyes were puffy and gritty.	
Anxiety		Feeling anxious	
Thinking abnormal		Racing thoughts	
Agitation			
Amnesia			
Confusional state			
Fatigue			Stopped aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 4D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prothiaden-aggressive

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142477 **Seq:** 1 **Gender:** F
Reported: 10/08/1999 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia		Numbness of her left side.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 2D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After 2 days of taking paroxetine symptoms recurred again. - the date of onset is not accurate but indicates that onset occurred sometime during the year.

Report Detail

Case Number: 142648 **Seq:** 1 **Gender:** M
Reported: 16/08/1999 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 13/07/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Dulled eye muscles seem to cause clumsy movements.	
Peripheral ischaemia		Feeling of cold or cold extremities.	
Tinnitus	Required Specialist Consultation	Patient experienced mild tinnitus.	
Arthralgia		Patient experienced occasional arthralgia.	
Dizziness		Rushing sensation across face, causing	Paroxetine 5 mg.
Drug withdrawal syndrome			
Fatigue			
Headache			

Medicine Details:

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 10/07/1999 **Stopped:** 17/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - cyclophosphamide iv, prednisolone and ees. patient taking 20mg aropax each morning for 17 months decided to wean himself off it. his approach was to take 10mg/day for a week then cease. the withdrawal effect was quite strong on 10mg/day thought at the time he develope d a cold and sinusitis to which he attibuted the sysmptoms. however after 2 weeks the symptoms are persistent. a surging sensation mainly through the head but diffusely throughout the body for a few seconds. movement of eye muscles produces a rushing sensation across face contributing to brief dizziness. turning head is accompanied by electrically-charged sensation as spinal muscle twist can be felt from head to toe. small precision

Report Detail

Case Number: 142648 **Seq:** 1 **Gender:** M
Reported: 16/08/1999 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 13/07/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching Vertigo			

Medicine Details:

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 10/07/1999 **Stopped:** 17/07/1999

Laboratory Investigations:

Additional Information:

See original report for other drug details - cyclophosphamide iv, prednisolone and ees. patient taking 20mg aropax each morning for 17 months decided to wean himself off it. his approach was to take 10mg/day for a week then cease. the withdrawal effect was quite strong on 10mg/day thought at the time he develope d a cold and sinusitis to which he attibuted the sysmptoms. however after 2 weeks the symptoms are persistent. a surging sensation mainly through the head but diffusely throughout the body for a few seconds. movement of eye muscles produces a rushing sensation across face contributing to brief dizziness. turning head is accompanied by electrically-charged sensation as spinal muscle twist can be felt from head to toe. small precision

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142652 **Seq:** 1
Reported: 16/08/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 74Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysphagia	Severe		Aropax therapy ceased.
Pneumonia	Severe		

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred one month after aropax commenced. patient has a medical history of motor neurone disease.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142744 **Seq:** 1 **Gender:** F
Reported: 18/08/1999 **Weight:** 53.00
Hospitalisation: **Age:** 20Y
Onset Date: 07/08/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous Urticaria	Severe	Erythematous skin rash Severe generalised symmetrical urticarial	Oral prednisolone.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 25/07/1999 **Stopped:** 08/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax increased to 20mg daily on 6/8/99. nil past history of allergy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142767 **Seq:** 1 **Gender:** F
Reported: 17/08/1999 **Weight:** 64.00
Hospitalisation: **Age:** 49Y
Onset Date: 07/08/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain Abdominal pain Vaginal haemorrhage		Sore breasts	 Provera, ponstan.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 26/07/1999 **Stopped:** 07/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142847 **Seq:** 1 **Gender:** M
Reported: 23/08/1999 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 31/07/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased		Patient experienced loss of libido.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/04/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142935 **Seq:** 1 **Gender:** F
Reported: 24/08/1999 **Weight:**
Hospitalisation: **Age:** 21Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			

Medicine Details:

ORAL CONTRACEPTIVE NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/10/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142938 **Seq:** 1 **Gender:** F
Reported: 24/08/1999 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Cant sleep	
Thinking abnormal		In a world of her own	
Depersonalisation		Zombie	
Hypoaesthesia			

Medicine Details:

NORMISON (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

VALIUM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Reducing Oral
Batch: **Started:** **Stopped:** 02D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142946 **Seq:** 1 **Gender:** F
Reported: 24/08/1999 **Weight:** 57.00
Hospitalisation: **Age:** 72Y
Onset Date: 07/08/1999 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Accommodation disorder		Couldnt focus	
Oculogyration		Eyes rolling around in head	
Dystonia		Jaw and neck tight	
Dizziness			
Headache			
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
0.5 Dose Unspecified Daily
Batch: **Started:** 07/08/1999 **Stopped:** 07/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction settled overnight and then recurred with another tablet. see original report for details of other drug therapy: fosimax, provera, premarin, lipex and multi mineral supplement.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142965 **Seq:** 1 **Gender:** F
Reported: 25/08/1999 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 18/08/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Drug withdrawal syndrome		Baby irritable,sucking continuously and	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother of baby taking paroxetine therapy throughout her pregnancy and is breastfeeding her baby.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 142967 **Seq:** 1 **Gender:** F
Reported: 25/08/1999 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 31/03/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Pollakiuria Urinary incontinence			Reduction of dose of aropax to 40mg/daily.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
80.0 Milligram Daily
Batch: **Started:** 08/01/1999 **Stopped:** 28/04/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

18/08/99 reduction of dose of aropax to 20mg/d due to recurrence of symptoms. see original report for more information of other drugs - temazepam, nitrazepa m, diazepam. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143395 **Seq:** 1 **Gender:** F
Reported: 02/09/1999 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorgasmia		Sexual side-effects.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143396 **Seq:** 1 **Gender:** F
Reported: 02/09/1999 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 21/12/1967
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensory disturbance Dizziness Drug withdrawal syndrome		"electric - like" shocks.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/06/1998 **Stopped:** 14M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also took 10 tablets of aropax with 2 bottles of wine on the 12/7/98 electric shocks jolt in head, lasting seconds. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143399 **Seq:** 1 **Gender:** M
Reported: 02/09/1999 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 05/11/1971
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue			Aropax therapy ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 L TERM **Stopped:** 13/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient immediately noticed an increase in energy after stopping medication. see original report for details of other drug. - xanax. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143400 **Seq:** 1 **Gender:** M
Reported: 02/09/1999 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 05/11/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Drug withdrawal syndrome		Intense and vivid nightmares.	Aropax therapy ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 L TERM **Stopped:** 13/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred 10 days after stopping therapy with aropax. patient had previously experienced symptoms on some nights since stopping aropax. see original report for details of other drug. - xanax. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143917 **Seq:** 1 **Gender:** F
Reported: 21/09/1999 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematoma Pain		Bilateral haematomas Groin pain	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143922 **Seq:** 1 **Gender:** M
Reported: 22/09/1999 **Weight:** 80.00
Hospitalisation: **Age:** 70Y
Onset Date: 18/09/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Tremor in left leg	Given diazepam. no further aropax - changed to zoloft.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram 1 time
Batch: **Started:** 18/09/1999 **Stopped:** 18/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had polio at 10yrs of age.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143926 **Seq:** 1 **Gender:** F
Reported: 22/09/1999 **Weight:** 60.00
Hospitalisation: **Age:** 69Y
Onset Date: 16/09/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations		Heart pounding	
Hyperkinesia		Hyperactive during day	
Headache			
Hyperhidrosis			
Insomnia			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 16/09/1999 **Stopped:** 16/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143961 **Seq:** 1 **Gender:** F
Reported: 23/09/1999 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 26/02/1952
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Apathy Dizziness		Vivid drreaming	

Medicine Details:

COVERSYL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CHLOTRIDE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

LOSEC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

LIPEX (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 143961 **Seq:** 1
Reported: 23/09/1999
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age: 47
DOB: 26/02/1952
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected)			Reason:	
Tablet	10.0	Milligram	Daily	Oral
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 144134 **Seq:** 1 **Gender:** F
Reported: 28/09/1999 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: 16/09/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Micturition disorder		Urinary retention	

Medicine Details:

MENOPREM (Suspected) **Reason:**
0.0 Dose Unspecified 1 time
Batch: **Started:** **Stopped:**

THYROXINE SODIUM (Suspected) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:**
800.0 Milligram Daily
Batch: **Started:** **Stopped:**

STELAZINE (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of allergies to penicillin, bactrim, serzone.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144134 **Seq:** 1
Reported: 28/09/1999
Hospitalisation:
Onset Date: 16/09/1999
Outcome: Not yet recovered

Gender: F
Weight:
Age: 49Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

KEMADRIN (Suspected)			**Reason:**	
	100.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
NORVASC (Suspected)			**Reason:**	
	10.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
SEREPAX (Suspected)			**Reason:**	
	30.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
TAZAC (Suspected)			**Reason:**	
	300.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

P/h of allergies to penicillin, bactrim, serzone.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144134 **Seq:** 1
Reported: 28/09/1999
Hospitalisation:
Onset Date: 16/09/1999
Outcome: Not yet recovered

Gender: F
Weight:
Age: 49Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:
P/h of allergies to penicillin, bactrim, serzone.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144364 **Seq:** 1 **Gender:** F
Reported: 06/10/1999 **Weight:** 63.00
Hospitalisation: **Age:** 68Y
Onset Date: 28/09/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 28/09/1999 **Stopped:** 05/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for more information of other drugs - lipitor, tazac, serevent, flixotide, dyazide. p/ h of allergies to theodur, nsaid, penicillin.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144387 **Seq:** 1 **Gender:** F
Reported: 06/10/1999 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 25/08/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema		Acute angioneurotic oedema	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 15/08/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144661 **Seq:** 1 **Gender:** F
Reported: 13/10/1999 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 17/04/1952
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypochromic anaemia		Patient experienced iron deficiency.	Iron tablets (1 tablet daily for 2-3 months).

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Patient developed low iron blood coutn (4-5mg/ml).

Additional Information:

Iron tablets were ceased in 1998. patient is now presenting again with persistent low blood iron (6mg/ml).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144696 **Seq:** 1 **Gender:** F
Reported: 14/10/1999 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 21/05/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotension		Bp 90/50.	
Dizziness		Giddiness 2 days after stopping treatment.	
Headache	Severe	Headaches upon gradually reducing dose to 20mg/day	
Drug withdrawal syndrome			Continued to decrease aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** 25/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details: prepulsid, panadeine, naprosyn, losec, & coloxyl. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144860 **Seq:** 1 **Gender:** F
Reported: 19/10/1999 **Weight:** 0.00
Hospitalisation: **Age:** 79
Onset Date: 19/06/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Inappropriate antidiuretic hormon		Suspected SIADH	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 17/06/1999 **Stopped:** 28/06/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - novasc, avapro, naprosyn, aldactone, mogadon, zocor, coloxyl and senna, serenace, panadol & ordine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144886 **Seq:** 1 **Gender:** M
Reported: 19/10/1999 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 27/05/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium Hyponatraemia			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 13/08/1998 **Stopped:** 27/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Concomitant lower respiratory tract infection with dehydration at presentation. severe depression in last 12 months - including 3 courses of ect. see original report for details of other drugs - ranitidine, temazepam, coloxyl with senna.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144900 **Seq:** 1 **Gender:** F
Reported: 19/10/1999 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 08/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Cease aropax, fluid restriction 1l/day, monitor u & e's.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/07/1999 **Stopped:** 13/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium	3.2-4.5	17/05/1999	2.9	
	Potassium	3.2-4.5	03/07/1999	3.8	
	Potassium	3.2-4.5	08/07/1999	3.4	
	Potassium	3.2-4.5	05/07/1999	3.6	
	Potassium	3.2-4.5	11/07/1999	4.1	
	Potassium	3.2-4.5	19/07/1999	4.6	
	Potassium	3.2-4.5	23/07/1999	4.3	

Additional Information:

Patient has a history of mild hyponatraemia. see original report for details of other drugs - ramipril, glyceryl trinitrate, panadeine, losec, calcitriol, coloxyl with senna, fgf, oxybutynin, dienoestrol cream.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144900 **Seq:** 1 **Gender:** F
Reported: 19/10/1999 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 08/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/07/1999 **Stopped:** 13/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium	3.2-4.5	20/07/1999	3.9	
	Potassium	3.2-4.5	14/07/1999	3.5	
	Potassium	3.2-4.5	10/07/1999	3.8	
	Sodium	135-145	17/05/1999	130	
	Sodium	135-145	03/07/1999	128	
	Sodium	135-145	05/07/1999	131	
	Sodium	135-145	08/07/1999	125	

Additional Information:

Patient has a history of mild hyponatraemia. see original report for details of other drugs - ramipril, glyceryl trinitrate, panadeine, losec, calcitriol, coloxyl with senna, fgf, oxybutynin, dienoestrol cream.

Report Detail

Case Number: 144900 **Seq:** 1 **Gender:** F
Reported: 19/10/1999 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 08/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/07/1999 **Stopped:** 13/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	135-145	10/07/1999	126	
	Sodium	135-145	11/07/1999	125	
	Sodium	135-145	14/07/1999	128	
	Sodium	135-145	19/07/1999	126	
	Sodium	135-145	20/07/1999	126	
	Sodium	135-145	23/07/1999	131	
	Urine osmolality	270-290	17/05/1999	258	

Additional Information:

Patient has a history of mild hyponatraemia. see original report for details of other drugs - ramipril, glyceryl trinitrate, panadeine, losec, calcitriol, coloxyl with senna, fgf, oxybutynin, dienoestrol cream.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144900 **Seq:** 1 **Gender:** F
Reported: 19/10/1999 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 08/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/07/1999 **Stopped:** 13/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Urine osmolality	270-290	03/07/1999	259	
	Urine osmolality	270-290	05/07/1999	267	
	Urine osmolality	270-290	08/07/1999	255	
	Urine osmolality	270-290	10/07/1999	252	
	Urine osmolality	270-290	11/07/1999	255	
	Urine osmolality	270-290	14/07/1999	264	
	Urine osmolality	270-290	19/07/1999	256	

Additional Information:

Patient has a history of mild hyponatraemia. see original report for details of other drugs - ramipril, glyceryl trinitrate, panadeine, losec, calcitriol, coloxyl with senna, fgf, oxybutynin, dienoestrol cream.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 144900 **Seq:** 1 **Gender:** F
Reported: 19/10/1999 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 08/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/07/1999 **Stopped:** 13/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Urine osmolality	270-290	20/07/1999	256	
	Urine osmolality	270-290	23/07/1999	264	

Additional Information:

Patient has a history of mild hyponatraemia. see original report for details of other drugs - ramipril, glyceryl trinitrate, panadeine, losec, calcitriol, coloxyl with senna, fgf, oxybutynin, dienoestrol cream.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145028 **Seq:** 1 **Gender:** F
Reported: 25/10/1999 **Weight:** 56.00
Hospitalisation: **Age:** 34Y
Onset Date: 31/08/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Hyperprolactinaemia			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 05/07/1999 **Stopped:** 16/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145043 **Seq:** 1 **Gender:** F
Reported: 25/10/1999 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 13/01/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Headache			Given analgesia. reduced aropax and then stopped.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** 02/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on aropax for approximately 2 and a half years. attempted to reduce dosage 12 months ago down to 1/4 tablet per day but experienced symptoms. increased dosage back up to 1 tablet per day. six months ago again reduced doasage to 1/2 tablet day. then stopped aropax altogether on 20/10/99 within one day, experienced symptoms which have not subsided after 4 days. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145044 **Seq:** 1 **Gender:** F
Reported: 25/10/1999 **Weight:** 65.00
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Spontaneous bruising around knee and	Dose of aropax tapered to 30mg then to 20mg over 1 month, but reccurence of depression symptoms

Medicine Details:

XANAX (Other drug) **Reason:**
500.0 Microgram As necessary
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 17/09/1999 **Stopped:** 14/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145061 **Seq:** 1 **Gender:** F
Reported: 26/10/1999 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue			Tiredness improved immediately with zoloft.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 02/06/1999 **Stopped:** 17/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of recovery: 9/99.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145210 **Seq:** 1 **Gender:** M
Reported: 29/10/1999 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: 08/08/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Headache		Funny feeling in head	

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 08/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on aropax 40mg daily went down to 20mg daily for two weeks then ceased on the 08/08/99.

Report Detail

Case Number: 145250 **Seq:** 1 **Gender:** F
Reported: 01/11/1999 **Weight:** 60.00
Hospitalisation: **Age:** 20Y
Onset Date: 30/09/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 30/09/1999 **Stopped:** 15/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of allergy to penicillin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145320 **Seq:** 1 **Gender:** F
Reported: 03/11/1999 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Dermatitis bullous Pruritus Rash vesicular		Chickenpox like rash	Patient referred to a dermatologist. aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** S TERM **Stopped:** 28/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rechallenge: the patient is now on a tapering-off dose of one quarter strength every two days and the rash has returned. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145321 **Seq:** 1
Reported: 03/11/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 29Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			Patient is now on a tapering-off dose of one-quarter strength every two days.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** S TERM **Stopped:** 28/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms were similar to those causedly a viral infection, that was then widespread in the community. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145431 **Seq:** 1 **Gender:** F
Reported: 03/11/1999 **Weight:** 107.00
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Insomnia Nausea Vomiting			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for other drug details - ventolin & flixotide. nil known allergies. patient took 0.5 tablet daily and experienced reaction 4-5 days after starting aropax. symptoms continued despite decreasing dose to every 2nd day.

Report Detail

Case Number: 145544 **Seq:** 1 **Gender:** F
Reported: 08/11/1999 **Weight:**
Hospitalisation: **Age:** 88
Onset Date: 13/09/1999 **DOB:** 28/08/1911
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Hypertonia		Decreased conscious state	Iv clonazepam. suspected drugs withdrawn.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 01/09/1999

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** 01/09/1999 **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
0.5 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions occurred 12 days after increasing dose of aropax from 20mg to 40mg.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145559 **Seq:** 1
Reported: 09/11/1999
Hospitalisation: Admitted to hospital
Onset Date: 22/08/1998
Outcome: Not yet recovered

Gender: M
Weight:
Age: 83Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal failure acute			Admitted to hospital

Medicine Details:

GLYCERYL TRINITRATE (Suspected) **Reason:** Unspecified schizophrenia
1.0 Dose Unspecified 1 time
Batch: **Started:** L TERM **Stopped:** 22/08/1998

DIGOXIN (Suspected) **Reason:** Chron isch heart dis no hyper
Tablet 2.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:** 22/08/1998

ANDROCUR (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:** 24/08/1998

LASIX (Suspected) **Reason:** Chron isch heart dis no hyper
Oral application 80.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 24/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine				Creatinine - 490.
	Potassium				Potassium - 5.4
	Serum drug level				Digoxin level - 4.5

Additional Information:

See original report for details of other drugs. - slow k and aspirin.

Report Detail

Case Number: 145559 **Seq:** 1
Reported: 09/11/1999
Hospitalisation: Admitted to hospital
Onset Date: 22/08/1998
Outcome: Not yet recovered

Gender: M
Weight:
Age: 83Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

CARDIZEM (Suspected)			**Reason:**	Chron isch heart dis no hyper	
Tablet	120.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	24/08/1998
AROPAX (Suspected)			**Reason:**	Chron isch heart dis no hyper	
Tablet	10.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	24/08/1998
MELLERIL (Suspected)			**Reason:**	Unspecified schizophrenia	
Tablet	10.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	24/08/1998
MACRODANTIN (Suspected)			**Reason:**	Unspecified schizophrenia	
	50.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	24/08/1998

Laboratory Investigations:

Additional Information:

See original report for details of other drugs. - slow k and aspirin.

Report Detail

Case Number: 145605 **Seq:** 1 **Gender:** F
Reported: 11/11/1999 **Weight:** 124.00
Hospitalisation: **Age:** 33Y
Onset Date: 06/08/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 06/08/1999 **Stopped:** 07/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145827 **Seq:** 1 **Gender:** F
Reported: 15/11/1999 **Weight:** 62.00
Hospitalisation: **Age:** 41Y
Onset Date: 21/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Agitation		Hot sting.sensa.over body similar to	

Medicine Details:

AROPAX (Suspected) **Reason:**
Injection 20.0 Milligram Daily Intramuscular
Batch: **Started:** 19/10/1999 **Stopped:** 21/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drugs: endep, murelax, cipramil. patient experienced symptoms 14 hours after aropax was taken, is prone to anxiety/panic atttack.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145837 **Seq:** 1 **Gender:** F
Reported: 15/11/1999 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 07/11/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			Ceased aropax.

Medicine Details:

COUMADIN (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:** 08/11/1999

AROPAX (Interaction) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/11/1999 **Stopped:** 09/11/1999

RYTHMODAN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CISAPRIDE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International		07/11/1999	3.9	
	International		09/11/1999	6	
	International		10/11/1999	5.4	

Additional Information:

Report Detail

Case Number: 145837 **Seq:** 1
Reported: 15/11/1999
Hospitalisation:
Onset Date: 07/11/1999
Outcome: Not yet recovered

Gender: F
Weight:
Age: 65Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ZOTON (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
IRBESARTAN (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
LIPEX (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
TEGRETOL (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145837 **Seq:** 1
Reported: 15/11/1999
Hospitalisation:
Onset Date: 07/11/1999
Outcome: Not yet recovered

Gender: F
Weight:
Age: 65Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

DIGOXIN (Other drug) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145840 **Seq:** 1 **Gender:** F
Reported: 15/11/1999 **Weight:** 70.00
Hospitalisation: **Age:** 59Y
Onset Date: 28/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Jerky movements	
Hyperhidrosis		Night sweats	
Abdominal pain			
Aggression			
Amnesia			
Confusional state			
Diarrhoea			
Tremor			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
0.5 Dose Unspecified Daily
Batch: **Started:** 22/10/1999 **Stopped:** 02/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drugs: losec, zocor, oroxine, cardizem.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145872 **Seq:** 1 **Gender:** F
Reported: 16/11/1999 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Required Visit to Doctor	Dizzy spells	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/03/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on hormone replacement therapy. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 145936 **Seq:** 1 **Gender:** M
Reported: 17/11/1999 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: 18/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Confusional state Dystonia Pyrexia		Severe muscle dystona	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:**
0.0
Batch: **Started:** 10/10/1999 **Stopped:** 18/10/1999

MOCLOBEMIDE (Interaction) **Reason:**
300.0 Milligram Daily
Batch: **Started:** 18/10/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See original report for details on other drugs: tegretol, epilim, murelax. had been told to stop paroxetine for 2 days prior to commencing moclobemide.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 146092 **Seq:** 1 **Gender:** F
Reported: 23/11/1999 **Weight:** 46.00
Hospitalisation: **Age:** 43Y
Onset Date: 28/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy	
Urticaria		Rash like hives	
Tremor		Unsteady	
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Ceased after 3 days.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 146124 **Seq:** 1 **Gender:** M
Reported: 24/11/1999 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Tongue oedema			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 16/11/1999 **Stopped:** 21/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 146418 **Seq:** 1 **Gender:** F
Reported: 01/12/1999 **Weight:** 52.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 04/01/1978
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities		Vater association syndrome confirmed at	

Medicine Details:

CANNABIS PREPARATION (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ILLICIT DRUGS (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Casual illicit drug use marajuanna, iv speed.

Additional Information:

Casual illicit drug use marajuanna and iv speed. pregnancy electively terminated at 20 weeks because of multiple abnormalities vater association syndrome confirmed at autopsy.

Report Detail

Case Number: 146563 **Seq:** 1 **Gender:** F
Reported: 06/12/1999 **Weight:** 48.00
Hospitalisation: **Age:** 33Y
Onset Date: 28/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glossitis		Sensation of burning tongue looks cracked.	Fluvoxamine ceased. recovered within 2 days.

Medicine Details:

OXAZEPAM (Other drug)			**Reason:**	Specific disorders of sleep
Oral application	30.0	Milligram	Daily	Oral
Batch:	**Started:**	15/10/1999	**Stopped:**	CONTIN
FLUVOXAMINE MALEATE (Suspected)			**Reason:**	Depression
Tablet	100.0	Milligram	Daily	Oral
Batch:	**Started:**	27/10/1999	**Stopped:**	18/11/1999
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression
Tablet	20.0	Milligram	Daily	Oral
Batch:	**Started:**	13/10/1999	**Stopped:**	26/10/1999
SODIUM VALPROATE (Suspected)			**Reason:**	Otr spec symp psychopathol nec
Tablet	600.0	Milligram	Daily	Oral
Batch:	**Started:**	20/10/1999	**Stopped:**	26/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 146573 **Seq:** 1 **Gender:** F
Reported: 06/12/1999 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 19/11/1999 **DOB:** 17/02/1979
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia Pharyngitis			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 20/11/1998 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

THYROXINE SODIUM (Suspected) **Reason:**
50.0 Microgram Daily
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:**
800.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		15/11/1998	7.4*	* pre-treatment results___** recent (amber range)
	Neutrophils		19/10/1999	6.4	* pre-treatment results___** recent (amber range)
	Neutrophils		19/11/1999	1.5-2.0**	* pre-treatment results___** recent (amber range)
	White blood cells		15/11/1998	11.0*	* pre-treatment results___** recent (amber range)
	White blood cells		19/10/1999	8.6	* pre-treatment results___** recent (amber range)
	White blood cells		19/11/1999	3.0-3.5**	* pre-treatment results___** recent (amber range)

Additional Information:

Sore throat occurred 1 year after starting clozaril.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 146656 **Seq:** 1 **Gender:** F
Reported: 07/12/1999 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: 24/09/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Nausea Palpitations			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified 1 time
Batch: **Started:** 23/09/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also on hrt (not specified) and takes ergodryl for migraines, not taken on day of aropax reaction.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 146685 **Seq:** 1 **Gender:** F
Reported: 09/12/1999 **Weight:** 65.00
Hospitalisation: **Age:** 48Y
Onset Date: 07/10/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Micturition disorder	Required Specialist Consultation		Therapy ceased

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 146713 **Seq:** 1
Reported: 08/12/1999
Hospitalisation: Admitted to hospital
Onset Date: 27/10/1999
Outcome: Recovered

Gender: F
Weight: 65.00
Age: 75Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 20/10/1999 **Stopped:** 01/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		27/10/1999	116	

Additional Information:

Hospital admission patient was also taking doxepin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 146817 **Seq:** 1 **Gender:** M
Reported: 13/12/1999 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 30/11/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

CALTRATE (Other drug) **Reason:** Other diseases of bone
1.8 Gram Daily
Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

AURORIX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 28/10/1999

OLANZAPINE (Suspected) **Reason:** Depression
1.0 Dose Unspecified 1 time
Batch: **Started:** 01/10/1999 **Stopped:** 29/11/1999

VALIUM (Suspected) **Reason:** Depression
1.0 Dose Unspecified 1 time
Batch: **Started:** 01/10/1999 **Stopped:** 29/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	(0-55)	30/11/1999	114	
	ALT = SGPT	(0-55)	07/12/1999	70	
	GGT = SGGT =	(0-60)	30/11/1999	113	
	GGT = SGGT =	(0-60)	07/12/1999	86	
	SAP = ALP	(30-110)	30/11/1999	109	
	SAP = ALP	(30-110)	07/12/1999	117	

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 146817 **Seq:** 1
Reported: 13/12/1999
Hospitalisation:
Onset Date: 30/11/1999
Outcome: Not yet recovered

Gender: M
Weight:
Age: 55Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected)		**Reason:**	Depression
	40.0 Milligram	Daily	
Batch:	**Started:** 01/10/1999	**Stopped:**	CONTIN
RANITIDINE (Suspected)		**Reason:**	Otr disorders stomach function
	300.0 Milligram	Daily	
Batch:	**Started:** 01/10/1999	**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Detail

Case Number: 146994 **Seq:** 1 **Gender:** F
Reported: 16/12/1999 **Weight:** 62.00
Hospitalisation: **Age:** 52Y
Onset Date: 08/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia			
Diarrhoea			
Dizziness			
Hyperkinesia			
Malaise			
Tremor			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 06/12/1999 **Stopped:** 10/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 147001 **Seq:** 1 **Gender:** F
Reported: 16/12/1999 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia	Required Specialist Consultation		
Diarrhoea	Required Specialist Consultation		
Fatigue	Required Specialist Consultation		
Nausea	Required Specialist Consultation		Aropax is taken at night.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 16/11/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 147058 **Seq:** 1 **Gender:** F
Reported: 17/12/1999 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: 20/11/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain		Breast tenderness and discomfort.	Aropax ceased.

Medicine Details:

ALEPAM (Other drug) **Reason:** Anxiety neurosis
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 147153 **Seq:** 1 **Gender:** F
Reported: 21/12/1999 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: 10/11/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Nausea			Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 10/11/1999 **Stopped:** 19/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 147371 **Seq:** 1 **Gender:** M
Reported: 23/12/1999 **Weight:**
Hospitalisation: **Age:** 70
Onset Date: **DOB:** 04/11/1929
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Required Visit to Doctor		Aropax ceased after second

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/04/1998 **Stopped:** 28/10/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking warfarin, doxycycline and other antibiotics (unknown). the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 147489 **Seq:** 1 **Gender:** M
Reported: 30/12/1999 **Weight:** 58.00
Hospitalisation: **Age:** 19
Onset Date: 01/12/1999 **DOB:** 25/06/1980
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Severe psychosis	Ceased aropax. antipyshotic medication initially

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 10/11/1999 **Stopped:** 28/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 147490 **Seq:** 1
Reported: 30/12/1999
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 57Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Constipation		Severe pain in lower abdomen.	Pethadeine and enema. ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 147767 **Seq:** 1 **Gender:** M
Reported: 06/01/2000 **Weight:** 78.00
Hospitalisation: **Age:** 68Y
Onset Date: 08/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Nausea		Head felt funny	

Medicine Details:

AROPAX (Suspected) **Reason:** Nervousness

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 07/12/1999 **Stopped:** 10/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking: plendil, renitec, & zocor.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 147788 **Seq:** 1 **Gender:** F
Reported: 07/01/2000 **Weight:** 60.00
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 11/09/1947
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Required Visit to Doctor	Hot outside and shivering inside.	
Abnormal dreams	Required Visit to Doctor	Vivid dreaming	
Dizziness	Required Visit to Doctor		Aropax 20mg to be taken on alternate days for a week and then stopped
Drug withdrawal syndrome	Required Visit to Doctor		
Nausea	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 148057 **Seq:** 1 **Gender:** F
Reported: 17/01/2000 **Weight:** 70.00
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 30/11/1970
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome	Required Visit to Doctor	At each dose reduction, experienced	5mg every second day.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on aropax 20mg/day for approximately 5-6 months. about 1 month ago, started to taper the dosage gradually. at each dose reduction, patient experienced dizziness. patient has now reduced dosage to 5mg every second day and her "dizziness is controllable". every time patient tries to stop medication completely, the dizziness becomes profound and she goes back to 5mg every second day.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 148110 **Seq:** 1 **Gender:** F
Reported: 17/01/2000 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 05/08/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema multiforme		Patient expereinced moderate erythema	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/09/1999 **Stopped:** 28/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking intel, ventolin and flixotide. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 148287 **Seq:** 1 **Gender:** F
Reported: 24/01/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage		Substantial gut bleeding	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 148337 **Seq:** 1 **Gender:** F
Reported: 27/01/2000 **Weight:** 56.00
Hospitalisation: **Age:** 65Y
Onset Date: 15/01/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Somnolence	Severe		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 14/01/2000 **Stopped:** 18/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking lexotan.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 148664 **Seq:** 1 **Gender:** U
Reported: 07/02/2000 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 22/06/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Loss of penile sensation	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 148857 **Seq:** 1 **Gender:** F
Reported: 11/02/2000 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention		Chronic urinary retention	Permanent in dwelling catheter

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) **Reason:**
Injection 10.0 Milligram 1 time Intramuscular
Batch: **Started:** 17/12/1999 **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 09/03/1999 **Stopped:**

OLANZAPINE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 21/05/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 149026 **Seq:** 1 **Gender:** F
Reported: 11/02/2000 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 18/01/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema Tongue oedema			

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 17/01/2000 **Stopped:** 19/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 149146 **Seq:** 1 **Gender:** F
Reported: 15/02/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Anxiety Hyperhidrosis		Trembling in the early part of the morning.	Serepax prn.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 10/01/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 149238 **Seq:** 1 **Gender:** F
Reported: 17/02/2000 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 05/05/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menstrual disorder		Experiencing very light periods of 1 day	

Medicine Details:

MONOFEME 28 (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/11/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 149471 **Seq:** 1 **Gender:** F
Reported: 18/02/2000 **Weight:** 50.00
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 31/01/2000 **Stopped:** 15/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has used zoloft for 6 weeks immediately prior.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 149530 **Seq:** 1 **Gender:** F
Reported: 22/02/2000 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 12/01/1952
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Muscle twitching		Pain in the back of legs.	 Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 18/12/1996 **Stopped:** 28/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 149573 **Seq:** 1 **Gender:** M
Reported: 17/02/2000 **Weight:**
Hospitalisation: **Age:** 95Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 40.0 Milligram Total Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking sinemet, lanoxin pg.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 149645 **Seq:** 1 **Gender:** F
Reported: 25/02/2000 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: 02/02/2000 **DOB:** 07/05/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Muscle spasm in jaw when yawning.	

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 149706 **Seq:** 1 **Gender:** M
Reported: 28/02/2000 **Weight:** 72.00
Hospitalisation: **Age:** 69
Onset Date: 06/02/2000 **DOB:** 17/08/1930
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Hot flush Hyperhidrosis Myalgia Thinking abnormal		Racing thoughts	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 04/02/2000 **Stopped:** 06/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prednisolone and temaze. p/h of allergy to quinine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 149892 **Seq:** 1 **Gender:** M
Reported: 02/03/2000 **Weight:** 85.00
Hospitalisation: **Age:** 23Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/10/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Blood test has shown raised alt and ast.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150085 **Seq:** 1 **Gender:** F
Reported: 08/03/2000 **Weight:** 68.00
Hospitalisation: **Age:** 41Y
Onset Date: 06/07/1998 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Pain in mouth & tongue, burning quality.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 05/02/1998 **Stopped:** 28/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prednisolone, serepax and cholrquin. reaction is worse at night. first commenced aropax jan 97, ceased april 97 not working. recommenced aropax early 98, off briefly oct 98. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150180 **Seq:** 1 **Gender:** M
Reported: 10/03/2000 **Weight:** 88.00
Hospitalisation: **Age:** 40Y
Onset Date: 23/02/2000 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Profuse sweating	Ceased aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 23/02/2000 **Stopped:** 25/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced same effects when he took another tablet of aropax next day.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150436 **Seq:** 1
Reported: 16/03/2000
Hospitalisation:
Onset Date: 11/03/2000
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 44Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax had been stopped some 3 days prior to starting luvox.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150509 **Seq:** 1 **Gender:** M
Reported: 17/03/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			

Medicine Details:

AROPAX (Suspected)		**Reason:** Depression		
Tablet	20.0 Milligram	Daily	Oral	
Batch:	**Started:** 10/02/2000		**Stopped:**	CONTIN
MELLERIL (Suspected)		**Reason:** Anxiety neurosis		
Tablet	100.0 Milligram	Daily	Oral	
Batch:	**Started:** 10/02/2000		**Stopped:**	CONTIN
XANAX (Suspected)		**Reason:** Anxiety neurosis		
Tablet	1.0 Milligram	Daily	Oral	
Batch:	**Started:** 10/02/2000		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150592 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Profuse sweating at night	Ceased aropax.

Medicine Details:

LEVLEN ED (Other drug) **Reason:** Contraception
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 25/05/1999 **Stopped:** 10/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150595 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:** 90.00
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nail disorder Alopecia		Brittle nails	 Changed to venlafaxine.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/06/1999 **Stopped:** 28/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking di-gesic, voltaren, temazeapm, provelle. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150718 **Seq:** 1 **Gender:** U
Reported: 23/03/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis Nausea Pruritus Pyrexia			

Medicine Details:

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:** CONTIN

TEGRETOL (Suspected) **Reason:**
400.0 Milligram Daily
Batch: **Started:** 01/01/2000 **Stopped:** 11/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT Bilirubin SAP = ALP				898, 29. 26, 13. 732, 153.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150906 **Seq:** 1
Reported: 28/03/2000
Hospitalisation:
Onset Date: 20/10/1999
Outcome: Not yet recovered

Gender: F
Weight: 105.00
Age: 30
DOB: 02/07/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Weight decreased			

Medicine Details:

RISPERDAL (Suspected) **Reason:** Unspecified psychosis
Oral application 1.0 Milligram Daily Oral
Batch: **Started:** 31/03/1998 **Stopped:**

ALDAZINE (Suspected) **Reason:** Specific disorders of sleep
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 24/06/1998 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 31/03/1998 **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:**
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 07/04/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Lost a lot of weight 15-20 kgs.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 150982 **Seq:** 1 **Gender:** F
Reported: 29/03/2000 **Weight:** 75.00
Hospitalisation: **Age:** 32Y
Onset Date: 08/03/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tetany Bruxism		Clenching jaw	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/03/2000 **Stopped:** 09/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 151160 **Seq:** 1 **Gender:** F
Reported: 03/04/2000 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 26/03/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Paraesthesia Nausea Throat tightness Tremor Vomiting Yawning		Pain in thoracic spine. Tingling of palms going down to legs.	Medication ceased, stemetil

Medicine Details:

AROPAX (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions occurred after second dose of aropax. patient also taking digesic, temazepam and atorvastatin.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 151246 **Seq:** 1 **Gender:** F
Reported: 05/04/2000 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 05/12/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death		Miscarriage at about 8 weeks of	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
1.0 Dose Unspecified 1 time
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had symptoms of threatened miscarriage such as bleeding before she had the tablet.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 151275 **Seq:** 1 **Gender:** M
Reported: 05/04/2000 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 15/06/1952
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Paraesthesia		Upon tapering of dose of aropax.	

Medicine Details:

ATENOLOL (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 151566 **Seq:** 1 **Gender:** F
Reported: 12/04/2000 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 27/05/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Lack of sleep	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms when dose of aropax was increased from 10mg to 20mg daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 151567 **Seq:** 1 **Gender:** F
Reported: 12/04/2000 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 27/05/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Nightmare			

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 15/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient abruptly stopped taking aropax a week ago and experienced symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 151859 **Seq:** 1
Reported: 19/04/2000
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 25Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Suspected serotonin syndrome.	

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 151899 **Seq:** 1 **Gender:** F
Reported: 20/04/2000 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 31/01/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Peripheral ischaemia		Raynaud's phenomenom	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 01/12/1999 **Stopped:** 28/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Positive cryoglobulins test.

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 152109 **Seq:** 1 **Gender:** F
Reported: 28/04/2000 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/03/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking alprazolam, becotide, nordette, ventolin. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 152116 **Seq:** 1 **Gender:** M
Reported: 28/04/2000 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Insomnia			Changed to serzone. given

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 14/12/1998 **Stopped:** 16/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not accurate but indicates that onset occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 152553 **Seq:** 1 **Gender:** F
Reported: 11/05/2000 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 11/01/1945
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Severe	Pain in various joints knees, elbow, thumb.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 20/11/1999 **Stopped:** 06/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking naprosyn, kalma, hrt. patient didn't have this problem at lower doses. onset of events 4-5 weeks ago when dose of aropax was incresed to 50mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 152637 **Seq:** 1 **Gender:** M
Reported: 15/05/2000 **Weight:** 75.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 152928 **Seq:** 1 **Gender:** F
Reported: 23/05/2000 **Weight:** 73.00
Hospitalisation: **Age:** 70
Onset Date: 16/05/2000 **DOB:** 25/12/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema Anorexia Diplopia Dry mouth Hyperhidrosis Nausea Tremor		Lip swelling	Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram 1 time Oral
Batch: **Started:** 16/05/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Commenced aropax 20mg 1 hour after first tab experienced symptoms. no history of allergies or previous use of this class of drug. patient was also taking monopril, norvasc, premarin, stemetil. patient recovered 19/5/00.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 152934 **Seq:** 1
Reported: 23/05/2000
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 22
DOB: 28/06/1977
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Hypomania	Aropax was ceased, admitted to hospital and given sodium

Medicine Details:

CANNABIS PREPARATION (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 07/04/1999 **Stopped:** 28/09/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 153034 **Seq:** 1 **Gender:** F
Reported: 24/05/2000 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 23/04/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Feeding disorder neonatal Drug withdrawal syndrome neona Nervousness Pyrexia Tremor		Poor feeding.	Supportive treatment - iv

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

CAFFEINE (Suspected) **Reason:**
0.0 Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby boy born 23/04/2000 (premature) 4 weeks. breast feeding appears to be of assistance. high intake of caffeine (2 lt coke + 10 - 12 cups of coffee per day) and paroxetine taken by mother during pregnancy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 153146 **Seq:** 1 **Gender:** F
Reported: 29/05/2000 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 12/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Purpuric rash on trunk, limbs.	Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 24/03/2000 **Stopped:** 14/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking zantac, coversyl, multiple vitamins, probiotics.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 153147 **Seq:** 1 **Gender:** F
Reported: 29/05/2000 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Drug withdrawal syndrome Insomnia Nightmare Tachycardia			Benzodiazepines.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 24/03/2000 **Stopped:** 14/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae-severe withdrawal symptoms. patient was also taking zantac, coversyl, multiple vitamins, probiotics.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 153153 **Seq:** 1 **Gender:** M
Reported: 29/05/2000 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 21/07/1964
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Required Visit to Doctor	Fear of heights	Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 22/09/1999 **Stopped:** 12/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking clozapine, cogentin, famotidine, maxepa, proctosedyl. patient experienced symptoms three months after initiating therapy with aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 153256 **Seq:** 1 **Gender:** M
Reported: 31/05/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 14/04/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			Warfarin ceased.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

WARFARIN SODIUM (Interaction) **Reason:** Phleb&thrombophleb lowr extrem
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 14/04/2000 **Stopped:** 16/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Inr remained high for 3/52 after cessation of warfarin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 153378 **Seq:** 1 **Gender:** M
Reported: 02/06/2000 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 13/12/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dermographism Urticaria			Symtoms did not settle with 5 days off aropex. will slowly

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropex reported previously to cause urticaria.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 153418 **Seq:** 1 **Gender:** F
Reported: 02/06/2000 **Weight:** 0.00
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion neonatal		Baby started fitting	
Drug withdrawal syndrome neona		Possibly displaying SSRI withdrawal symptoms	Resuscitated by paediatrician with routine management for fitting
Cyanosis		Went dusky blue	
Bradykinesia		Within 2 minutes of delivery, episode of bradykinesia	
Encephalopathy neonatal		developed encaphalopathy of unknown cause, believed to be caused by bacterial infection	
Apgar score low			
Postmature baby			

Medicine Details:

AROPAX (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 06/10/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Other data				Apgar scores that fell from 7 at one minute to five at five minutes

Additional Information:

Commenced Aropax on 15.6.99 at 23 weeks of pregnancy. The dose was initially 10mg and this was increased to 20mg after three days. On 29.6.99 at 25 weeks, the dose was increased to 30mg daily. On 9.8.99 at 31 weeks, the dose was increased through to 50mg per day. She remained on this until after the delivery. Ten days post-delivery, on 26.10.99 the dose was increased to 60mg per day. he mother's membrane ruptured the day before delivery. Continuous follow-up until baby settled. Born on 16/10/99 and discharged from neonatal nursery on 24/10/99. Dr believes baby would have experienced even even if mother had not been on Aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 153636 **Seq:** 1 **Gender:** M
Reported: 13/06/2000 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 31/01/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased	Required Visit to Doctor	Loss of libido.	
Erectile dysfunction	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 01/12/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking risperidone. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Report Detail

Case Number: 153676 **Seq:** 1 **Gender:** F
Reported: 15/06/2000 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice		After 5 days of treatment pt become	Xanax therapy ceased.

Medicine Details:

ZOTON (Suspected)			**Reason:**		
Tablet	1.0	Dose Unspecified	As necessary		Oral
Batch:	**Started:**			**Stopped:**	
XANAX (Suspected)			**Reason:**	Depression	
Tablet	4.5	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
AROPAX (Suspected)			**Reason:**	Depression	
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Bil 171, sap 314, ggt 247, alt 1015, ast 579.

Additional Information:

Report Detail

Case Number: 153850 **Seq:** 1 **Gender:** M
Reported: 20/06/2000 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 31/03/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia	Required Visit to Doctor	Moderate gynacomastia	Reduced aropax from 40mg to 20mg daily.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was very well on aropax 20mg. had a virus and required a higher dose of 40mg. responded well but developed symptoms after a few months. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154016 **Seq:** 1 **Gender:** F
Reported: 22/06/2000 **Weight:** 76.00
Hospitalisation: **Age:** 36
Onset Date: 08/01/1996 **DOB:** 11/09/1959
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death		Stillborn at 38 weeks	

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154017 **Seq:** 1 **Gender:** F
Reported: 22/06/2000 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 31/08/1996 **DOB:** 11/09/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death		Miscarriage twins 8.5 weeks and 10 weeks	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154018 **Seq:** 1 **Gender:** F
Reported: 22/06/2000 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 06/06/1997 **DOB:** 11/09/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotonia neonatal		Live birth 06/06/1997 induced at 37 weeks	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Live birth 6/6/97 - induced at 37 weeks - initial low tone on apgar. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154019 **Seq:** 1 **Gender:** F
Reported: 22/06/2000 **Weight:** 76.00
Hospitalisation: **Age:** 40
Onset Date: 18/04/2000 **DOB:** 11/09/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Agitation neonatal Drug withdrawal syndrome neona Hypotonia neonatal		Baby irritable for first 10 days	Aropax ceased

Medicine Details:

AROPAX (Suspected)			**Reason:** Depression		
Tablet	50.0 Milligram		Daily	Oral	
Batch:	**Started:** 01/01/1995			**Stopped:**	CONTIN
TERTROXIN (Suspected)			**Reason:**		
Tablet	10.0 Microgram		Daily	Oral	
Batch:	**Started:** 25/03/1999			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Live birth 18/04/00 at 35.5 weeks. apgar's 4 at 1 minute, 7 at 5 minutes, 10 at 10 minutes (low tone). the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154232 **Seq:** 1 **Gender:** M
Reported: 28/06/2000 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 06/04/1964
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paranoia Depersonalisation		Feel weired, funny in head, paranoid	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 20/06/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154289 **Seq:** 1 **Gender:** F
Reported: 28/06/2000 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 14/06/2000 **DOB:** 05/07/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Required Visit to Doctor		
Syncope	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 14/06/2000 **Stopped:** 14/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154389 **Seq:** 1 **Gender:** F
Reported: 01/07/2000 **Weight:** 60.00
Hospitalisation: **Age:**
Onset Date: 19/06/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia Pain Paraesthesia		Myalgia in left leg.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 18/06/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had stopped prothiaden on 13/6/00.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154438 **Seq:** 1 **Gender:** F
Reported: 05/07/2000 **Weight:** 55.00
Hospitalisation: **Age:** 70
Onset Date: 31/01/2000 **DOB:** 20/01/1930
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life	Fluid retention electrolyte disturbance.	Date of recovery: 03/2000.
Pulmonary oedema	Life		

Medicine Details:

LANOXIN (Other drug) **Reason:** Left ventricular failure
0.2 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

RENITEC (Other drug) **Reason:** Left ventricular failure
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
5.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

SOTALOL HYDROCHLORIDE (Other drug) **Reason:** Otr&nos disord of heart rhythm
160.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Syndrome of inappropriate a.d.h. secretion. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154438 **Seq:** 1
Reported: 05/07/2000
Hospitalisation:
Onset Date: 31/01/2000
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 70
DOB: 20/01/1930
Causality: Causality probable

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Syndrome of inappropriate a.d.h. secretion. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154501 **Seq:** 1
Reported: 07/07/2000
Hospitalisation: Admitted to hospital
Onset Date: 26/06/2000
Outcome: Not yet recovered

Gender: M
Weight: 106.00
Age: 61Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastric ulcer haemorrhage			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 12/06/2000 **Stopped:** 02/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Microbiology				H.pylori positive.
	Other data				G.i.h secondary to large gastric ulcer proven on endoscopy.

Additional Information:

Patient was also taking salbutamol ma and budesonide. paroxetine was initiated 21 days prior to admission to hospital.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154532 **Seq:** 1 **Gender:** F
Reported: 06/07/2000 **Weight:** 55.00
Hospitalisation: **Age:** 39
Onset Date: 23/06/2000 **DOB:** 15/01/1961
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysgeusia Agitation		Very strong unpleasant metallic taste.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 19/06/2000 **Stopped:** 24/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking serepac and protaphane.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 154587 **Seq:** 1
Reported: 06/07/2000
Hospitalisation: Admitted to hospital
Onset Date: 04/06/2000
Outcome: Recovered

Gender: F
Weight:
Age: 43
DOB: 21/10/1956
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Burning up the arms and feet.	Advised to take half a tablet the next day.
Tachycardia		Heart was racing.	
Dizziness			

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: 86512 **Started:** 03/06/2000 **Stopped:** 04/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Half a tablet was taking the next day and the same symptoms occurred and was taken by ambulance to the hospital again. batch number: 86512.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155542 **Seq:** 1 **Gender:** F
Reported: 27/07/2000 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 14/08/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Dizziness Drug withdrawal syndrome Nightmare		Night sweats	

Medicine Details:

SERENACE (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/09/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on aropax 40mg/day for approximately 12 months. has recently fallen pregnant. dosage reduced from 40mg/day to 20mg/day, since confirmation of pregnancy, patient has experienced symptoms since dose has been reduced. female baby was born 24/4/00 with a preauricular skin tag left ear, audiology normal, developing normally. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155571 **Seq:** 1
Reported: 28/07/2000
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 79.00
Age: 36
DOB: 22/01/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Dizziness Nausea		Off balance, unsteady on her feet.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/01/1998 **Stopped:** 28/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155594 **Seq:** 1 **Gender:** F
Reported: 27/07/2000 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 22/06/2000 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Severe	"severe" hypomanic episode.	Aropex ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/04/2000 **Stopped:** 28/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Approximetely 2 months after administration of aropax therapy patient developed symptoms. patient has no family history of hypomania/mania and no history of episodes. aropax therapy was rechallenged causing the same reaction patient also taking - thyroxine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155668 **Seq:** 1 **Gender:** M
Reported: 31/07/2000 **Weight:**
Hospitalisation: **Age:** 16Y
Onset Date: 16/07/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension		Elevated systolic blood pressure,	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

THIORIDAZINE HYDROCHLORIDE (Suspected) **Reason:** Otr spec symp psychopathol nec
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TEMAZEPAM (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155705 **Seq:** 1 **Gender:** F
Reported: 31/07/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 15/06/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia			

Medicine Details:

PREMARIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PRAVACHOL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

LIPEX (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155709 **Seq:** 1 **Gender:** F
Reported: 31/07/2000 **Weight:** 67.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

METHOTREXATE (Suspected) **Reason:**
10.0 Milligram Weekly
Batch: **Started:** 01/01/1998 **Stopped:**

ARAVA (Suspected) **Reason:** Other rheumatoid arthritis
20.0 Milligram Daily
Batch: **Started:** 01/03/2000 **Stopped:** 28/07/2000

ZANTAC (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

CELEBREX (Suspected) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	5 - 40	11/08/2000	71	
	ALT = SGPT	5 - 40	31/08/2000	46	
	ALT = SGPT	5 - 40	22/09/2000	24	
	ALT = SGPT	5 - 40	30/10/2000	33	
	ALT = SGPT	5 - 40	10/10/2000	29	
	AST = SGOT	5 - 40	11/08/2000	55	
	AST = SGOT	5 - 40	31/08/2000	37	

Additional Information:

Patient also taking capoten, tenormin, panafcort, orudis sr, panadeine, progynova. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155709 **Seq:** 1 **Gender:** F
Reported: 31/07/2000 **Weight:** 67.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	5 - 40	10/10/2000	22	
	AST = SGOT	5 - 40	22/09/2000	23	
	AST = SGOT	5 - 40	30/10/2000	23	
	Bilirubin	3 - 20	11/08/2000	5	
	Bilirubin	3 - 20	31/08/2000	5	
	Bilirubin	3 - 20	22/09/2000	<3	
	Bilirubin	3 - 20	10/10/2000	3	

Additional Information:

Patient also taking capoten, tenormin, panafcort, orudis sr, panadeine, progynova. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Report Detail

Case Number: 155709 **Seq:** 1
Reported: 31/07/2000
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 67.00
Age: 70Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

METHOTREXATE (Suspected)		**Reason:**	
	10.0 Milligram	Weekly	
Batch:	**Started:** 01/01/1998		**Stopped:**
ARAVA (Suspected)		**Reason:**	Other rheumatoid arthritis
	20.0 Milligram	Daily	
Batch:	**Started:** 01/03/2000		**Stopped:** 28/07/2000
ZANTAC (Suspected)		**Reason:**	
	300.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
CELEBREX (Suspected)		**Reason:**	
	200.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	3 - 20	30/10/2000	3	
	GGT = SGGT = ASAT	5 - 65	11/08/2000	141	
	GGT = SGGT = ASAT	5 - 65	31/08/2000	78	
	GGT = SGGT = ASAT	5 - 65	22/09/2000	46	
	GGT = SGGT = ASAT	5 - 65	10/10/2000	39	
	GGT = SGGT = ASAT	5 - 65	30/10/2000	39	
	SAP = ALP	30 - 115	11/08/2000	83	

Additional Information:

Patient also taking capoten, tenormin, panafcort, orudis sr, panadeine, progynova. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155709 **Seq:** 1
Reported: 31/07/2000
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 67.00
Age: 70Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	30 - 115	31/08/2000	69	
	SAP = ALP	30 - 115	22/09/2000	53	
	SAP = ALP	30 - 115	10/10/2000	54	
	SAP = ALP	30 - 115	30/10/2000	61	

Additional Information:

Patient also taking capoten, tenormin, panafcort, orudis sr, panadeine, progynova. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155728 **Seq:** 1 **Gender:** F
Reported: 01/08/2000 **Weight:** 45.00
Hospitalisation: **Age:** 44
Onset Date: 27/03/2000 **DOB:** 20/07/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Dase tetrated down to 10mg per every 5-6 day. required a visit to doctor. date of recovery 08/05/00

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 01/02/2000 **Stopped:** 28/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar reaction to 100mg zoloft in 1996. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 155858 **Seq:** 1 **Gender:** M
Reported: 04/08/2000 **Weight:** 86.00
Hospitalisation: **Age:** 68Y
Onset Date: 07/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema Anorexia Nausea		Swelling of ankles.	Ceased aropax, fluid restriction. patient was admitted from rehab post a previous admission, was commenced on aropax while in rehab.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 29/11/1999 **Stopped:** 09/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking digoxin, ranitidine, lasix, theodur, prednisolone, captopril, slow-k, ventolin/atrovent, serevent, flixotide. allergic to panadeine forte.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 156033 **Seq:** 1 **Gender:** M
Reported: 10/08/2000 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia Tremor		Choreiform movements upper & lower extremities/jaw	 Maxolon treatment was stopped and aropax was ceased spprox. 2 weeks ago.

Medicine Details:

MAXOLON (Suspected) **Reason:**
10.0 Milligram As necessary
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/05/1999 **Stopped:** 28/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 156197 **Seq:** 1 **Gender:** F
Reported: 10/08/2000 **Weight:**
Hospitalisation: **Age:** A4
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthritis Antinuclear antibody positive		Poly arthralgia	

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 7D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Antinuclear factor				Raised ana titre

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 156198 **Seq:** 1 **Gender:** F
Reported: 10/08/2000 **Weight:**
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 10/01/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Dizziness Hot flush Palpitations Tremor		Severe dragging pain in the stomach	

Medicine Details:

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 156449 **Seq:** 1 **Gender:** M
Reported: 15/08/2000 **Weight:** 80.00
Hospitalisation: **Age:** 16
Onset Date: **DOB:** 24/06/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe rash.	Antihistamine (phenergan) orally and prednisolone orally. treated in outpatient section of hospital. aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 06/01/2000 **Stopped:** 07/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 156759 **Seq:** 1
Reported: 24/08/2000
Hospitalisation: Admitted to hospital
Onset Date: 27/06/2000
Outcome: Recovered

Gender: F
Weight:
Age: 57Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			Diazepam and cyproheptadine.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:** 27/06/2000

NORTRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:** Depression
0.0
Batch: **Started:** **Stopped:** 27/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 30/6/00.

Report Detail

Case Number: 156858 **Seq:** 1 **Gender:** F
Reported: 28/08/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Metrorrhagia			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

DEPO-PROVERA (Suspected) **Reason:** Contraception
Injection 150.0 Milligram As necessary Intramuscular
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient received 6th injection of depo provera, was initiated on aropax and wihin several days experienced breakthrough bleeding.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 156910 **Seq:** 1
Reported: 25/08/2000
Hospitalisation:
Onset Date: 19/08/2000
Outcome: Not yet recovered

Gender: M
Weight: 100.00
Age: 48
DOB: 18/02/1952
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Urticarial rash on extremeties.	Required a visit to doctor. antihistamine/topical treatment.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 11/08/2000 **Stopped:** 19/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 157178 **Seq:** 1 **Gender:** M
Reported: 31/08/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 17/06/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vasculitis		Alleergic cutaneous vasculitis	
Oedema peripheral		Oedema hands/feet.	
Pruritus			
Rash erythematous			Phenergan, prednisolone, telfast. aropax ceased. date of recovery 01/07/00

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
40.0 Milligram Daily
Batch: **Started:** 01/06/2000 **Stopped:** 19/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been on aropax 20mg from 01/06/00. increased dose to 40mg/day on 17/06/00 with sudden onset of reaction.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 157204 **Seq:** 1 **Gender:** M
Reported: 29/08/2000 **Weight:**
Hospitalisation: **Age:** 63Y
Onset Date: 18/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			Date of recovery 19/08/00

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 18/08/2000 **Stopped:** 18/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking daonil, diabex, indocid, insulin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 157248 **Seq:** 1 **Gender:** F
Reported: 31/08/2000 **Weight:**
Hospitalisation: **Age:** 70
Onset Date: 01/07/2000 **DOB:** 06/05/1930
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glaucoma Visual disturbance	Required Specialist Consultation		Aropax reduced to 10mg/d.treated with latanoprost

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 13/06/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 157497 **Seq:** 1 **Gender:** F
Reported: 06/09/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 01/09/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation		Paroxysmal atrial fibrillation rate 140.	Iv magnesium, sotalol. required a visit to doctor. date of [illegible]

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 01/09/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking erythromycin. onset occurred 1 hour after taking paroxetine hcl.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 157517 **Seq:** 1 **Gender:** F
Reported: 07/09/2000 **Weight:** 56.00
Hospitalisation: **Age:** 33Y
Onset Date: 01/09/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Atrial fibrillation Hyperhidrosis Nausea Vomiting	Severe	Severe headache	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram 1 time Oral
Batch: **Started:** 01/09/2000 **Stopped:** 01/09/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg: 7 hours after onset showed paroxysm atrial fibrillation

Additional Information:

Patient experienced symptoms after taking 1st dose of aropax. patient recovered 2/9/00.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 157628 **Seq:** 1 **Gender:** F
Reported: 06/08/2000 **Weight:**
Hospitalisation: **Age:** 22
Onset Date: **DOB:** 20/06/1978
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death		Pt had a miscarriage a blighted ovum	

Medicine Details:

AROPAX (Suspected) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was three weeks pregnant.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 157984 **Seq:** 1 **Gender:** F
Reported: 22/09/2000 **Weight:** 68.00
Hospitalisation: **Age:** 55
Onset Date: 31/08/1999 **DOB:** 21/03/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Osteoarthritis		Constant joint pains. Possible swelling.	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/08/1999 **Stopped:** 17/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Worse after sitting and in arm, ie arthritis. joint pains decreased, still residual joint pains but less. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158072 **Seq:** 1 **Gender:** U
Reported: 25/09/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

BENZTROPINE MESYLATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158084 **Seq:** 1
Reported: 25/09/2000
Hospitalisation: Treated in outpatient department only.
Onset Date: 20/04/2000
Outcome: Recovered

Gender: F
Weight:
Age: 41Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain		Dull/constant chest pain	
Abdominal pain		Epigastric pain radiated to chest after 12	
Pruritus		Generalised itch	
Flushing		Hot flushed face.	
Nausea			Anginine-3 tablets releived pain after 10 minutes, maxolon

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

Batch: **Started:** 20/04/2000 **Stopped:** 21/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms half an hour after taking aropax tablet. patient was also taking thyroxine and flagyl. allergies: penicillin-rash, erythromycin-diarrhoea. patient recovered 21/4/00.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158170 **Seq:** 1 **Gender:** F
Reported: 27/09/2000 **Weight:** 78.00
Hospitalisation: **Age:** 21Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Talipes		Fetus with talipes	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 08/05/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				19 weeks pregnant. routine ultrasound shows fetus with talipes.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158318 **Seq:** 1 **Gender:** U
Reported: 09/10/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 25/07/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Nausea Vomiting			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
10.0 Milligram 1 time
Batch: **Started:** 24/07/2000 **Stopped:** 24/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158323 **Seq:** 1 **Gender:** M
Reported: 09/10/2000 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 02/08/2000 **DOB:** 28/09/1940
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Paroxetine ceased.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 23/07/2000 **Stopped:** 02/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 158447 **Seq:** 1
Reported: 09/10/2000
Hospitalisation: Admitted to hospital
Onset Date: 01/08/2000
Outcome: Not yet recovered

Gender: U
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Admitted to emergency department, catheter idc.

Medicine Details:

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep

Oral application 10.0 Milligram As necessary Oral

Batch: **Started:** S TERM **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 23/07/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No known allergies.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158529 **Seq:** 1 **Gender:** F
Reported: 16/10/2000 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: 31/03/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Photosensitive eczematous rash.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 01/02/2000 **Stopped:** 23/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158797 **Seq:** 1 **Gender:** M
Reported: 25/10/2000 **Weight:**
Hospitalisation: **Age:** 56
Onset Date: 12/10/2000 **DOB:** 04/07/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia Diarrhoea Dizziness Dry mouth Nausea			Required a visit to doctor. date of recovery 17.10.00.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 12/10/2000 **Stopped:** 16/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158847 **Seq:** 1
Reported: 25/10/2000
Hospitalisation: Admitted to hospital
Onset Date: 29/09/2000
Outcome: Not yet recovered

Gender: M
Weight:
Age: 26
DOB: 14/12/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
550.0 Milligram Daily
Batch: **Started:** 29/02/2000 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				29/9/00: ecg showed sinus rhythm.
	Other data				29/09/00: echocardiography showed mild septal left ventricular hyperthrophy with mild dyskinesia: global contraction within normal limits. normal aortic valve, mobile mitral valve leaflets. normal left atrial size. left ventricular size and systolic contraction are within normal limits? mild septal dyskinesis normal wall thickness. simpson's ejection fraction = 49%. right heart appears
	Other data				Normal. no pericardial effusion. mild septal left ventricular hypertrophy with mild dyskinesia: global contraction within normal limits

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 158847 **Seq:** 1
Reported: 25/10/2000
Hospitalisation: Admitted to hospital
Onset Date: 29/09/2000
Outcome: Not yet recovered

Gender: M
Weight:
Age: 26
DOB: 14/12/1973
Causality: Causality possible

Reaction Detail

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
550.0 Milligram Daily
Batch: **Started:** 29/02/2000 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				1/9/00: clozapine level 364 ng/ml.

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 159011 **Seq:** 1
Reported: 01/11/2000
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 30
DOB: 23/10/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Constipation Weight increased			Given coloxyl plus fibre plus dietry management.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

1.0 Dose Unspecified Daily

Batch: **Started:** 08/09/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No history of constipation prior to aropax, no significant changes in fluids/ diet, depression well-controlled.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 159153 **Seq:** 1 **Gender:** F
Reported: 08/11/2000 **Weight:** 80.00
Hospitalisation: **Age:** 30Y
Onset Date: 29/10/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state Drug withdrawal syndrome Insomnia Nausea			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 11/07/2000 **Stopped:** 26/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on paroxetine for 4 months. after 3rd day of nil medication patient experienced symptoms. patient recommenced paroxetine 1/11/00 and recovered 2/11/00.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 159167 **Seq:** 1 **Gender:** M
Reported: 09/11/2000 **Weight:** 80.00
Hospitalisation: **Age:** 46
Onset Date: 01/11/2000 **DOB:** 24/11/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Drug withdrawal syndrome Fatigue Muscle twitching Paraesthesia Somnolence			Recovered instantly when aropax 10mg added to 20mg. totally recovered when aropax returned to 40mg/day. date of recovery 6.11.00.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram 1 time
Batch: **Started:** 31/10/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Profound withdrawal commenced 8 hours after taking aropax 20mg mane instead of 40mg mane taken until previous day.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 159291 **Seq:** 1 **Gender:** F
Reported: 16/11/2000 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: 20/10/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Involuntary partial biting movement of jaw.	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 13/10/2000 **Stopped:** 23/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking zantac. patient was on aropax 10mg from 9/10/00 to 13/10/00, then was increased to 20mg from the 13/10/00 to 23/10/00. patient recovered 26/10/00.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 159314 **Seq:** 1
Reported: 16/11/2000
Hospitalisation: Admitted to hospital
Onset Date: 15/10/2000
Outcome: Recovered

Gender: U
Weight:
Age: 26
DOB: 24/05/1974
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Hyperglycaemia	Severe		Patient taken to emergency department with type 1 diabetes on 15/10/00 and subsequently admitted to hospital.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 10/04/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 159315 **Seq:** 1
Reported: 16/11/2000
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 52.00
Age: 66
DOB: 10/01/1934
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension Anxiety Hyperhidrosis Myalgia Neurosis		Bp 220/120	Patient hospitalised.

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 159747 **Seq:** 1 **Gender:** M
Reported: 05/12/2000 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 31/05/2000 **DOB:** 05/10/1973
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Cardiomegaly Cardiomyopathy Tachycardia			Treated with carvedilol.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** 09/05/1996 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 2.0 Milligram Daily Oral

Batch: **Started:** 01/01/1999 **Stopped:**

CLONAZEPAM (Suspected) **Reason:**

Tablet 500.0 Microgram Daily Oral

Batch: **Started:** 01/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data Other data				Diagnosed with cardiomyopathy on echocardiography in may 2000, 4 years after commencing clozaril. repeat echocardiography on 24 oct 2000 detected a worsening of the patients condition. nov 2000 echocardiogram: mild to moderate cardiomyopathy. A cardiac ultrasound in july 2000 showed cardiomegaly with intact systolic and normal diastolic flow parameters. an echocardiogram on 24 oct 2000 showed further increase in cardiomegaly and deterioration in lv systolic function at rest. estimated ejection fraction of around 35 - 40%

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 159887 **Seq:** 1
Reported: 09/12/2000
Hospitalisation:
Onset Date: 09/12/2000
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 36
DOB: 03/09/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction			Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prednisolone, flixotide, ventolin. has a history of many drug adverse reaction.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 160035 **Seq:** 1 **Gender:** F
Reported: 14/12/2000 **Weight:** 94.00
Hospitalisation: **Age:** 63
Onset Date: 20/11/2000 **DOB:** 27/07/1937
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema Oedema peripheral Pruritus			Required a visit to doctor. date of recovery 08/12/00

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking noten, imdur, rani, astrix, sotalol, zocor, diazepam. p/h of allergy to zoloft - itching

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 160073 **Seq:** 1
Reported: 18/12/2000
Hospitalisation:
Onset Date: 31/03/2000
Outcome: Not yet recovered

Gender: F
Weight: 90.00
Age: 39
DOB: 20/04/1960
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Carbohydrate crawings	Changed medication, required a visit to doctor.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

30.0 Milligram Daily

Batch: **Started:** 01/03/2000 **Stopped:** 28/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Weight gain of 3 and a half stone.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 160231 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:** 57.00
Hospitalisation: **Age:** 66Y
Onset Date: 31/08/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Lofenoxal 1 tds. metsal

Medicine Details:

METSAL (Suspected) **Reason:** Sciatica
Ointment 0.0 Topical
Batch: **Started:** 01/10/1999 **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

COVERSYL (Suspected) **Reason:** Essential benign hypertension
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

FRUSEMIDE (Suspected) **Reason:** Essential benign hypertension
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 160231 **Seq:** 1
Reported: 22/12/2000
Hospitalisation:
Onset Date: 31/08/2000
Outcome: Not yet recovered

Gender: F
Weight: 57.00
Age: 66Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ISCOVER (Suspected)			**Reason:**		
Tablet	75.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
NORVASC (Suspected)			**Reason:**	Essential benign hypertension	
Tablet	5.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

- the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 160269 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:** 55.00
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Diarrhoea Muscle twitching Palpitations			

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:** Pain
6.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 14/12/2000 **Stopped:** 18/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 160295 **Seq:** 1 **Gender:** F
Reported: 28/12/2000 **Weight:** 55.00
Hospitalisation: **Age:** 66
Onset Date: 21/09/2000 **DOB:** 28/05/1934
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin ulcer		Arms and legs.	
Pruritus		Generalised pruritus.	Required a visit to doctor. date of recovery 14.12.00. aropax ceased
Skin depigmentation		Patch depigmentation remains.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 15/06/2000 **Stopped:** 01/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking thyroxine and karvezide.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161025 **Seq:** 1 **Gender:** F
Reported: 29/01/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cyanosis neonatal		Small ventricular septal defect in baby.	Baby was given antibiotics, then put onto a nasogastric

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** 01/05/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother took aropax during pregnancy from may 2000 and is still on aropax. child was born 21/11/00 and put into special care unit straight away as he had a heart murmur. on the 22/11/00 it was noticed he was slightly blue and iv antibiotics were commenced as it was thought he could have some infection. on 23/11/00 he was being sick whilst feeding and was turning really blue. the infant was then put onto a nasogastric tube and has made good progress. it is expected that his cardiac condition will resolve. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161167 **Seq:** 1
Reported: 02/02/2001
Hospitalisation: Admitted to hospital
Onset Date: 27/01/2001
Outcome: Unknown

Gender: M
Weight:
Age: 38
DOB: 28/11/1962
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Priapism			Patient was hospitalised.

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking clozapine and sodium vlaproate.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161284 **Seq:** 1
Reported: 08/02/2001
Hospitalisation: Admitted to hospital
Onset Date: 31/01/2001
Outcome: Not yet recovered

Gender: F
Weight: 62.00
Age: 29
DOB: 01/03/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Massive muscle spasms	Admiited to hospital and given
Hyperreflexia		Sluggish reflexes.	
Tongue oedema		Swollen tongue	
Dysphonia		Voice went high	
Tremor			

Medicine Details:

DIANE-35 ED (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 31/01/2001 **Stopped:** 31/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161307 **Seq:** 1
Reported: 08/02/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/02/2001
Outcome: Unknown

Gender: M
Weight:
Age: 43
DOB: 09/11/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Loss of reality, didn't know where to put	Valium, temazepam. patient hospitalised. date of recovery 02/01/01.

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 30/01/2001 **Stopped:** 01/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161314 **Seq:** 1 **Gender:** F
Reported: 09/02/2001 **Weight:** 58.00
Hospitalisation: **Age:** 28Y
Onset Date: 13/07/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			

Medicine Details:

LOGYNON ED (Other drug) **Reason:** Contraception
1.0 Dose Unspecified Daily
Batch: **Started:** 14/04/1998 **Stopped:**

CANNABIS PREPARATION (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 13/07/1998 **Stopped:** 27/08/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161329 **Seq:** 1 **Gender:** M
Reported: 12/02/2001 **Weight:** 73.00
Hospitalisation: **Age:** A4
Onset Date: 05/02/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		In head and travelling down neck to arms	Paroxetine ceased.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/11/2000 **Stopped:** 04/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161345 **Seq:** 1 **Gender:** M
Reported: 08/02/2001 **Weight:**
Hospitalisation: **Age:** 75
Onset Date: 22/01/2001 **DOB:** 27/12/1925
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ascites Hepatic failure Hepatic necrosis Renal failure acute Respiratory failure			Patient admitted to hospital. date of death 04/02/01.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 25/10/2000 **Stopped:** 21/01/2001

NALTREXONE HYDROCHLORIDE (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 20/01/2001 **Stopped:** 21/01/2001

PARACETAMOL (Suspected) **Reason:** Morb&mort due otr ill-def caus
3.0 Gram Daily
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:** Depression
250.0 Gram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		22/01/2001	2535	
	AST = SGOT		22/01/2001	5203	
	Albumin		22/01/2001	34	
	Bilirubin		22/01/2001	137	
	International normalised ratio		22/01/2001	4.6	
	LDH		22/01/2001	2442	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161345 **Seq:** 1
Reported: 08/02/2001
Hospitalisation:
Onset Date: 22/01/2001
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 75
DOB: 27/12/1925
Causality: Causality possible

Reaction Detail

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:** Depression	
	10.0 Milligram	Daily		
Batch:	**Started:** 25/10/2000		**Stopped:** 21/01/2001	
NALTREXONE HYDROCHLORIDE (Suspected)			**Reason:**	
	50.0 Milligram	Daily		
Batch:	**Started:** 20/01/2001		**Stopped:** 21/01/2001	
PARACETAMOL (Suspected)			**Reason:** Morb&mort due otr ill-def caus	
	3.0 Gram	Daily		
Batch:	**Started:**		**Stopped:**	
ALCOHOL (Suspected)			**Reason:** Depression	
	250.0 Gram	Daily		
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Toxicology summary report 5/3/01: 1. the blood contained a subtherapeutic concentration of presumptively identified paracetamol. alcohol was not detected in the blood. no other common drugs including paroxetine were detected in the blood. note: the laboratory does not currently have a method for naltrexone and zopiclone.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161450 **Seq:** 1
Reported: 14/02/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 90.00
Age: 79
DOB: 24/09/1921
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myositis Blood creatine phosphokinase in Myalgia		Polymyositis.	Required a visit to doctor. patient was hospitalised.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/01/2000 **Stopped:** 28/02/2000

AROPAX (Suspected) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 28/02/2000 **Stopped:** 09/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine Muscle biopsy		15/01/2001	1300	Muscle biopsy suggest polymyositis.

Additional Information:

Patient also taking neulactil, astrix, tazac, serepax and normison.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161591 **Seq:** 1
Reported: 15/02/2001
Hospitalisation:
Onset Date: 12/02/2001
Outcome: Not yet recovered

Gender: F
Weight: 80.00
Age: 26
DOB: 26/06/1974
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia Headache Tremor		Spasm, locked jaw.	Required a visit to doctor. date of recovery 13/02/01.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 12/02/2001 **Stopped:** 13/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking norimin, ventolin.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161625 **Seq:** 1 **Gender:** F
Reported: 16/02/2001 **Weight:** 55.00
Hospitalisation: **Age:** 71Y
Onset Date: 30/11/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension Hyponatraemia		Bp 120/80 -> 90/70 symptomatic.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/06/2000 **Stopped:** 30/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Na 119.

Additional Information:

Patient also taking oxazepam, atrovent and budesonide. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161642 **Seq:** 1 **Gender:** M
Reported: 19/02/2001 **Weight:** 75.00
Hospitalisation: **Age:** 42
Onset Date: 01/10/1998 **DOB:** 22/04/1956
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eye pain Glaucoma		Inflamed eye pain both eyes. Intraocular tension 37-45	Ceased paroxetine, required a visit to doctor.

Medicine Details:

XANAX (Other drug) **Reason:** Anxiety neurosis
1.0 Milligram Daily
Batch: **Started:** 01/10/1997 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 01/10/1997 **Stopped:** 28/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Intraocular tension 37-45.

Additional Information:

the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161690 **Seq:** 1
Reported: 16/02/2001
Hospitalisation: Admitted to hospital
Onset Date: 22/01/2001
Outcome: Recovered

Gender: F
Weight: 56.00
Age: 27
DOB: 28/04/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death			Patient hospitalised

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

30.0 Milligram Daily

Batch: **Started:** 01/01/1998 **Stopped:** 07/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Malformation of embryo at 9/52.

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161891 **Seq:** 1 **Gender:** F
Reported: 26/02/2001 **Weight:** 65.00
Hospitalisation: **Age:** 56Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain from 8 stone to 10 1/2 over 4 [illegible]	Diet restricted no weight loss and limited exercise.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 30/10/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has been treated with aropax previously with similar response and ceased drug, but relapsed with depression.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161996 **Seq:** 1 **Gender:** U
Reported: 26/02/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 27/12/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Hyponatraemia Inappropriate antidiuretic hormon			Fluid restriction, paroxetine ceased

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 29/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum osmolality		27/12/2000	258	
	Sodium		27/12/2000	121	
	Sodium		29/12/2000	122	
	Sodium		31/12/2000	125	
	Sodium		01/01/2001	130	
	Sodium		04/01/2001	134	
	Urine Sodium		27/12/2000	79	

Additional Information:

Patient also taking nilstat, dexamethasone, temazepam, metoclopramide, paracet amol, ranitidine, flucloxacillin.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 161996 **Seq:** 1 **Gender:** U
Reported: 26/02/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 27/12/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Oral application 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 29/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Urine osmolality		27/12/2000	523	

Additional Information:

Patient also taking nilstat, dexamethasone, temazepam, metoclopramide, paracet amol, ranitidine, flucloxacillin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 162212 **Seq:** 1 **Gender:** F
Reported: 05/03/2001 **Weight:** 80.00
Hospitalisation: **Age:** 41
Onset Date: 31/12/2000 **DOB:** 22/11/1959
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Cardiomyopathy and muscle twinges in face, lips and arms, weight gain, and a generalised feeling of heaviness.	Tritace 2.5 mg to be increased to 5 mg
Weight increased		Cardiomyopathy and muscle twinges in face, lips and arms, weight gain, and a generalised feeling of heaviness.	Tritace 2.5 mg to be increased to 5 mg
Cardiomyopathy			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 01/01/2000 **Stopped:** 31/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/03/2001	Echocardiogram				
05/03/2001	Echocardiogram				
05/03/2001	Echocardiogram				

Additional Information:

Noted to have early dilated cardiomyopathy. initially no treatment started. Reviewed 6/12 later - back to normal. In this recovery period she had stopped Aropax and noted that she felt 100% better. Aropax was recommenced in May 2001 and stopped agin in May 2002 (ie. rechallenge).The date of onset is not accurate but indicates that onset occurred sometime during the year. The dosage start date is not accurate but indicates that start occurred sometime during the year. The dosage stop date is not accurate but indicates that stoppage occurred sometime during the year. Also taking Ventolin and Sudafed.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 162434 **Seq:** 1 **Gender:** F
Reported: 09/03/2001 **Weight:** 63.00
Hospitalisation: **Age:** 63Y
Onset Date: 24/02/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Choking		Choking feeling.	
Thinking abnormal		Funny in the head.	
Hot flush		Hot, sudden heat.	
Hypoaesthesia		Numb leg.	
Oedema		Swollen throat.	Aropax ceased 27.2.01.
Malaise			
Somnolence			

Medicine Details:

AROPAX (Suspected) **Reason:**
0.5 Dose Unspecified Daily
Batch: **Started:** 24/02/2001 **Stopped:** 27/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking estraderm, prednisolone, periactin, aspirin and brufen. patient took aropax for 1 month in 1999 but doesn't remember any problems. may have taken prednisolone, did take brufen, periactin, aspirin and estraderm on day of reaction as well as aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 162784 **Seq:** 1 **Gender:** U
Reported: 19/03/2001 **Weight:** 76.00
Hospitalisation: **Age:** 44
Onset Date: 20/02/2001 **DOB:** 22/08/1956
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Tremor			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 15/02/2001 **Stopped:** 23/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking noten, lipitor. patient recovered 14/3/01.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 162864 **Seq:** 1 **Gender:** F
Reported: 19/03/2001 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 28/07/1956
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus			Required a visit to doctor. moisturising ointments.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 01/02/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No known allergies. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163026 **Seq:** 1 **Gender:** F
Reported: 27/03/2001 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 21/02/2001 **DOB:** 27/01/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		1 week of throbbing headache.	Required a visit to doctor.
Dizziness		Dizzy and pressure in head.	
Drug withdrawal syndrome		Drug withdrawal reaction.	
Paraesthesia	Required Specialist Consultation	Mild pins and needles.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 01/02/2000 **Stopped:** 21/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had been on 20mg paroxetine for 12/12. reduced to 10mg for 1/12 the ceased. 1/52 of severe withdrawal symptoms, no diarrhoea. patient also taking risperidone.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163235 **Seq:** 1
Reported: 02/04/2001
Hospitalisation:
Onset Date: 08/12/2000
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 25
DOB: 22/08/1975
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Required Visit to Doctor	Increased axillary sweating.	Declined to restart Aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/12/2000 **Stopped:** 10/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

163235 is a seq to 163236.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163236 **Seq:** 1 **Gender:** M
Reported: 02/04/2001 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: 11/03/2001 **DOB:** 22/08/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Increased after aropax ceased, persisting	
Dizziness	Required Visit to Doctor		
Drug withdrawal syndrome	Required Visit to Doctor		Aropax ceased.
Nausea	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/12/2000 **Stopped:** 10/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Declined to restart aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163304 **Seq:** 1
Reported: 02/04/2001
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 30
DOB: 03/01/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Nausea - worse with movement, is getting	Treated with stemitil.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 01/01/1999 **Stopped:** 03/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

the dosage start date is not accurate but indicates that start occurred sometime during the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163317 **Seq:** 1 **Gender:** F
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** 56Y
Onset Date: 26/03/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope Paraesthesia Hypertonia Anxiety Somnolence		Collapsed and near loss of consciousness. Electric shocks on arms and legs. Muscle spasms in abdo particularly, but all	Treated with valium.

Medicine Details:

AROPAX (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** 26/03/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking naprosyn and panadol. had total hysterectomy on 14.3.01. discharged 20.3.01 but readmitted 20.3.01 due to severe abdominal haematoma and pain+++. changed from panadeine forte to digesic for pain relief in hospital. discharged 26.3.01 - took first dose of aropax approx 10am that day. reaction occurred approx 11am. last dose of digesic approx 1pm 25.3.01.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163441 **Seq:** 1 **Gender:** F
Reported: 05/04/2001 **Weight:** 57.00
Hospitalisation: **Age:** 49
Onset Date: 30/03/2001 **DOB:** 13/03/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Hallucination Paraesthesia			Body tingling.

Medicine Details:

ZYPREXA (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

VAGIFEM (Other drug) **Reason:**
Suppository 50.0 Microgram Weekly Vaginal
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:**
Capsule 4.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

MOGADON (Other drug) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Body tingling as last ime ceased aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163441 **Seq:** 1 **Gender:** F
Reported: 05/04/2001 **Weight:** 57.00
Hospitalisation: **Age:** 49
Onset Date: 30/03/2001 **DOB:** 13/03/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

RANI 2 (Other drug)			**Reason:**	
Tablet	150.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
IMODIUM (Other drug)			**Reason:**	
Capsule	4.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
FLAGYL (Other drug)			**Reason:**	
Tablet	1.2	Gram	Daily	Oral
Batch:	**Started:**			**Stopped:**
PREMARIN (Other drug)			**Reason:**	
Tablet	625.0	Microgram	Daily	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:
Body tingling as last ime ceased aropax.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163441 **Seq:** 1
Reported: 05/04/2001
Hospitalisation:
Onset Date: 30/03/2001
Outcome: Unknown

Gender: F
Weight: 57.00
Age: 49
DOB: 13/03/1952
Causality: Causality possible

Reaction Detail

Medicine Details:

CELEBREX (Other drug)			**Reason:**		
Capsule	400.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
AROPAX (Suspected)			**Reason:**		
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	29/03/2001

Laboratory Investigations:

Additional Information:

Body tingling as last ime ceased aropax.

Report Detail

Case Number: 163504 **Seq:** 1 **Gender:** F
Reported: 06/04/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence Choking Coma Constipation Salivary hypersecretion Vomiting		Bedwetting	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 1.2 Gram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

RISPERIDONE (Suspected) **Reason:**
6.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163594 **Seq:** 1
Reported: 09/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 27/03/2001
Outcome: Unknown

Gender: M
Weight:
Age: 36
DOB: 30/11/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium Drug level increased		Acute delirium. Elevated clozapine levels	Admitted to hospital

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 450.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** CONTIN

AROPAX (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 07/03/2001 **Stopped:** 29/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163744 **Seq:** 1
Reported: 13/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 31/01/2001
Outcome: Recovered

Gender: M
Weight:
Age: 30
DOB: 03/09/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Euphoric mood	Required Visit to Doctor	"feeling high". moderate euphoria.	Patient required hospitalisation. aropax therapy ceased.
Dizziness	Required Visit to Doctor	Moderate dizziness.	
Suicide attempt	Required Visit to Doctor	Moderate suicidal ideation.	
Somnolence	Severe	Severe drowsiness.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 01/11/2000 **Stopped:** 28/01/2001

ALCOHOL (Suspected) **Reason:**
Oral application 4.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient consumed 4 to 5 glasses of beer/wine. the dose start and the dose stop date for the drug aropax are not necessarily accurate but indicates the drug was started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 163946 **Seq:** 1 **Gender:** F
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Limb reduction defect		Baby born with limb defects.	

Medicine Details:

AROPAX (Suspected) **Reason:** Angina pectoris w/o hyperten

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby was born with limb defects and his mother had been on aropax 20mg daily from 4-7 weeks of gestation. right arm: distal arm is smaller than left. absent 5th digit, small 3rd digit, syndactyly of 2nd, 3rd and 4th fingers. right leg: lower leg is smaller than left. cleft between 1st and 2nd toes, syndactyly of 2nd, 3rd and 4th, 5th toes.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 164292 **Seq:** 1 **Gender:** F
Reported: 04/05/2001 **Weight:** 53.00
Hospitalisation: **Age:** 29Y
Onset Date: 28/04/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain - (3 kg).	No treatment.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 25/01/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 164454 **Seq:** 1 **Gender:** F
Reported: 11/05/2001 **Weight:**
Hospitalisation: **Age:** 16
Onset Date: 08/04/2001 **DOB:** 14/12/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Babbling	
Anxiety		Distraughtness.	
Coordination abnormal		Lack of coordination	
Hypertonia		Muscle tenseness and jaw locked.	
Thinking abnormal		Thoughts racing	
Dizziness			
Dyspepsia			
Headache			
Nausea			Ginger and chamomile. had to seek medical help.
Tremor			

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 0.2 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 164519 **Seq:** 1 **Gender:** M
Reported: 14/05/2001 **Weight:** 75.00
Hospitalisation: **Age:** 62
Onset Date: 28/12/2000 **DOB:** 05/04/1938
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Flushing		Excessive sweating and flushes.	Required a visit to doctor. aropax ceased. date of recovery: 27/4/2001

Medicine Details:

ASASANTIN SR (Other drug) **Reason:** Phleb&thrombophleb lowr extrem
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 01/12/2000 **Stopped:** 26/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for aropax is not necessarily accurate but indicates aropax was started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 164558 **Seq:** 1 **Gender:** F
Reported: 16/05/2001 **Weight:** 68.00
Hospitalisation: **Age:** 35
Onset Date: 23/04/2001 **DOB:** 25/05/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema		Swollen face	
Oedema peripheral		Swollen limbs	
Tongue oedema		Swollen tongue	
Muscle twitching			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 21/04/2001 **Stopped:** 23/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 164683 **Seq:** 1
Reported: 21/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 08/05/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 33
DOB: 26/04/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Conjunctival haemorrhage Muscle twitching Purpura Vomiting	Severe		Patient was hospitalised. ivt for hyperemesis.

Medicine Details:

FOLIC ACID (Other drug) **Reason:** Other vitamin b deficiency
0.5 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 08/05/2001 **Stopped:** 08/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No known allergies.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 164811 **Seq:** 1
Reported: 24/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 03/05/2001
Outcome: Recovered

Gender: F
Weight:
Age: 57
DOB: 15/04/1944
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain Myocardial infarction			Patient hospitalised.

Medicine Details:

CARDIZEM CD (Other drug) **Reason:** Essential benign hypertension
Capsule 180.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZANTAC (Other drug) **Reason:** Prophylaxis
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

WARFARIN SODIUM (Other drug) **Reason:** Acute myocard infarc,no hypert
0.0 Daily
Batch: **Started:** **Stopped:**

ASPIRIN (Other drug) **Reason:** Acute,ill-def cerebrovascular disease w/o hyperte
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				(n) angiography post am.

Additional Information:

Report Detail

Case Number: 164811 **Seq:** 1
Reported: 24/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 03/05/2001
Outcome: Recovered

Gender: F
Weight:
Age: 57
DOB: 15/04/1944
Causality: Causality possible

Reaction Detail

Medicine Details:

LASIX (Other drug)			**Reason:**	Essential benign hypertension
	40.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
SLOW-K (Other drug)			**Reason:**	Other specified symptoms nec
	1.0	Dose Unspecified	Daily	
Batch:	**Started:**			**Stopped:**
LIPITOR (Other drug)			**Reason:**	Othr&unspec metabolic diseases
	20.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
AROPAX (Suspected)			**Reason:**	Depression
Tablet	20.0	Milligram	Daily	Oral
Batch:	**Started:**	19/04/2001		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 164980 **Seq:** 1
Reported: 30/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/03/2001
Outcome: Recovered with sequelae

Gender: F
Weight:
Age: AD
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Heart disease congenital		Life threatening, severe.	Pt hospitalised.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on aropax 10mg until 12 weeks pregnant and then on aropax 20 mg daily. baby born on 03/03/01 with heart malformation

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 164981 **Seq:** 1
Reported: 30/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 19/02/2001
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 38
DOB: 19/01/1963
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities Congenital eye disorder		Baby suffers from choanal atresia Left eye hypoplasia (blind)	Hospitalised.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt took aropax throughout pregnancy (started prior to pregnancy by 2 years) baby born with significant defects. the dose start date is not accurate but indicates the drug was started sometim e in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 165248 **Seq:** 1 **Gender:** F
Reported: 08/06/2001 **Weight:** 71.00
Hospitalisation: **Age:** 43
Onset Date: 01/06/2001 **DOB:** 14/11/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Very rapid paroxysmal tachycardia ?svt.	Aproax ceased. required a visit to doctor.

Medicine Details:

NUROFEN (Other drug) **Reason:**
0.0
Batch: **Started:** 31/05/2001 **Stopped:**

PANADOL (Other drug) **Reason:**
0.0
Batch: **Started:** 31/05/2001 **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 04/03/2001 **Stopped:** 02/04/2001

ERGODRYL MONO (Suspected) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 31/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 165477 **Seq:** 1 **Gender:** F
Reported: 18/06/2001 **Weight:** 59.00
Hospitalisation: **Age:** 60Y
Onset Date: 06/02/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response unexpecte			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 10/05/1999 **Stopped:** CONTIN

BUPROPION HYDROCHLORIDE (Interaction) **Reason:** Smoker
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 06/02/2001 **Stopped:** 07/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Full remission of narcoleptic condition during course of bupropion, with relapse on cessation. was also successful in stopping smoking.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 165509 **Seq:** 1 **Gender:** F
Reported: 01/06/2001 **Weight:** 73.00
Hospitalisation: **Age:** 24
Onset Date: 28/01/1999 **DOB:** 14/08/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysarthria Hypoaesthesia		Feels like slurred speech. Intermittent tongue numbness	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start is not necessarily accurate but indicates aropax was started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 165630 **Seq:** 1 **Gender:** F
Reported: 20/06/2001 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 28/09/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Pruritus		Rash through hair, over face, whole body	Claratyne, zyrtec, sorbolene cream, phenergan, celebrex changed to vioxx, all medications discontinued one by one. required a visit to doctor and specialist.

Medicine Details:

PARADEX (Suspected) **Reason:**
Tablet 2.0 Dose Unspecified As necessary Oral
Batch: **Started:** L TERM **Stopped:**

ATROBEL (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** L TERM **Stopped:**

CELEBREX (Suspected) **Reason:**
Capsule 200.0 Milligram Daily Oral
Batch: **Started:** 01/08/2000 **Stopped:** 28/08/2000

TRISEQUENS (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start & stop date is not necessarily accurate but indicates celebrex was started and stopped sometime in the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 165630 **Seq:** 1
Reported: 20/06/2001
Hospitalisation:
Onset Date: 28/09/2000
Outcome: Not yet recovered

Gender: F
Weight:
Age: 36Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

IMODIUM (Suspected)			**Reason:**		
Capsule	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	
AROPAX (Suspected)			**Reason:**		
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	
ZANTAC (Suspected)			**Reason:**		
Tablet	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	
NORMISON (Suspected)			**Reason:**		
Oral application	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	

Laboratory Investigations:

Additional Information:

The dose start & stop date is not necessarily accurate but indicates celebrex was started and stopped sometime in the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 165630 **Seq:** 1
Reported: 20/06/2001
Hospitalisation:
Onset Date: 28/09/2000
Outcome: Not yet recovered

Gender: F
Weight:
Age: 36Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

NASONEX AQUEOUS NASAL SPRAY (Suspected) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Additional Information:

The dose start & stop date is not necessarily accurate but indicates celebrex was started and stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 165668 **Seq:** 1 **Gender:** F
Reported: 20/06/2001 **Weight:**
Hospitalisation: **Age:** 71Y
Onset Date: 28/11/2000 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Particularly at night, in bed and during	Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** 01/11/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cessation of drug in the past, but restarted the drug due to significant benefit on mood. reaction continues. the patient claims she also experienced restless legs with aurorix and lovan a s well. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates the drug was sta rted sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 166084 **Seq:** 1
Reported: 25/06/2001
Hospitalisation:
Onset Date: 07/05/2001
Outcome: Not yet recovered

Gender: F
Weight: 72.00
Age: 36
DOB: 22/10/1964
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Disociated.	
Paraesthesia		Tingling extremities.	Required a visit to doctor. reaction was life threatening. relieved by reintroduction of aropax
Drug withdrawal syndrome			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 03/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 166345 **Seq:** 1 **Gender:** F
Reported: 11/07/2001 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 20/06/2001 **DOB:** 28/09/1953
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Drug withdrawal syndrome Insomnia Nausea Tinnitus			

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax dose was 20mg --> 10mg and later 10mg --> to 0mg.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 166352 **Seq:** 1 **Gender:** M
Reported: 12/07/2001 **Weight:** 72.00
Hospitalisation: **Age:** 20
Onset Date: 19/06/2001 **DOB:** 19/11/1980
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Pyrexia			Ceased aropax

Medicine Details:

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep

Oral application 10.0 Milligram As necessary Oral

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 05/06/2001 **Stopped:** 05/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recovered 6/7/01. influenza and blood culture serology negative. negative fbe, elft, esr, tsh.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 166497 **Seq:** 1 **Gender:** M
Reported: 18/07/2001 **Weight:** 100.00
Hospitalisation: **Age:** 67
Onset Date: 05/07/2001 **DOB:** 17/01/1934
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations			Ceased aropax. date of recovery 17/07/2001. required

Medicine Details:

DICHLOTRIDE (Other drug) **Reason:** Essential benign hypertension
25.0 Milligram Daily
Batch: **Started:** 20/03/2001 **Stopped:** CONTIN

TRITACE (Other drug) **Reason:** Essential benign hypertension
15.0 Milligram Daily
Batch: **Started:** 12/09/2000 **Stopped:** CONTIN

SOLPRIN (Other drug) **Reason:** Chron isch heart dis no hyper
0.0 Daily
Batch: **Started:** **Stopped:** CONTIN

PRAVACHOL (Other drug) **Reason:** Othr&unspec metabolic diseases
20.0 Milligram Daily
Batch: **Started:** 12/09/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 166497 **Seq:** 1
Reported: 18/07/2001
Hospitalisation:
Onset Date: 05/07/2001
Outcome: Recovered

Gender: M
Weight: 100.00
Age: 67
DOB: 17/01/1934
Causality: Causality probable

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/07/2000 **Stopped:** 07/07/2000

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 166705 **Seq:** 1
Reported: 23/07/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 62
DOB: 22/08/1938
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy Agitation		Indifferent face	 Patient admitted to hosptial

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:** Otr spec symp psychopathol nec
15.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:** Anxiety neurosis
10.0 Milligram Daily
Batch: **Started:** 18/12/2000 **Stopped:** 16/06/2001

XANAX (Suspected) **Reason:** Specific disorders of sleep
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also developed bizaar repetitive movements.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 166705 **Seq:** 1
Reported: 23/07/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 62
DOB: 22/08/1938
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 17/11/2000 **Stopped:** CONTIN

Laboratory Investigations:

Additional Information:

Patient also developed bizaar repetitive movements.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 167078 **Seq:** 1 **Gender:** M
Reported: 01/08/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Confusional state Hypertension Serotonin syndrome		Profuse sweating	Ceased aropax and aricept.

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 05/06/2001 **Stopped:** 25/07/2001

ARICEPT (Interaction) **Reason:**
5.0 Milligram Daily
Batch: **Started:** 19/07/2001 **Stopped:** 25/07/2001

TRANDOLAPRIL (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 29/05/2001 **Stopped:**

SOTALOL HYDROCHLORIDE (Other drug) **Reason:**
320.0 Milligram Daily
Batch: **Started:** 29/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 167078 **Seq:** 1 **Gender:** M
Reported: 01/08/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Medicine Details:

OXAZEPAM (Other drug) **Reason:**
22.0 Milligram Daily
Batch: **Started:** 07/07/2001 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 167484 **Seq:** 1
Reported: 17/05/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 63
DOB: 03/05/1938
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Drug withdrawal syndrome Migraine			Patient was hospitalised. patient usually takes a sandomigran tablet to treat migrains, however it was inefficacious. patient then took a fiorinal tablet and this was also ineffective.

Medicine Details:

TEGRETOL (Other drug) **Reason:**

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 167497 **Seq:** 1 **Gender:** F
Reported: 13/08/2001 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 16/06/2001 **DOB:** 31/07/1967
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams		Unusual, vivid, disturbing dreams of [illegible]	Aropax dose reduced to 10mg mane on 23/7/01 and ceased completely on 30/7/01. date of recovery: 5/8/01

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/05/2001 **Stopped:** 30/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 167718 **Seq:** 1
Reported: 20/08/2001
Hospitalisation:
Onset Date: 01/08/2001
Outcome: Not yet recovered

Gender: F
Weight: 58.00
Age: 18
DOB: 29/12/1982
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Nausea Paraesthesia Tremor			Required visit to doctor. paroxetine re-instated.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 01/08/1999 **Stopped:** 01/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The onset date, and the dose start and stop dates for paroxetine are not necessarily accurate but indicate the onset date sometime in august 2001 and the dose start date sometime in aug 1999 and stop date in aug 2001.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168281 **Seq:** 1 **Gender:** M
Reported: 10/09/2001 **Weight:** 85.00
Hospitalisation: **Age:** 40
Onset Date: 25/08/2001 **DOB:** 18/04/1961
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction Hallucination			Stopped taking aropax.

Medicine Details:

LOSEC (Other drug) **Reason:** Other diseases of esophagus
20.0 Milligram Daily
Batch: **Started:** 01/06/2000 **Stopped:**

CECLOR (Other drug) **Reason:** Chronic sinusitis
2.0 Dose Unspecified Daily
Batch: **Started:** 02/08/2001 **Stopped:** 07/08/2001

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 5/9/01.

Report Detail

Case Number: 168293 **Seq:** 1 **Gender:** F
Reported: 10/09/2001 **Weight:**
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Agitation		Aggression over last few days. Increased agitation.	 Cessation of tramadol and use of other analgesics.

Medicine Details:

AROPAX (Interaction) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain
200.0 Milligram Daily
Batch: **Started:** 21/07/2001 **Stopped:**

VENTOLIN (Other drug) **Reason:**
2.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergies: sulphur, macrodantin. history: coad - smoker, cholecystectomy, hysterectomy, knee arthroscopy.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168293 **Seq:** 1 **Gender:** F
Reported: 10/09/2001 **Weight:**
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

TEMAZEPAM (Other drug)		**Reason:**	
	10.0 Milligram	As necessary	
Batch:	**Started:**		**Stopped:**
SEREVENT ACCUHALER (Other drug)		**Reason:**	
	200.0 Microgram	Daily	
Batch:	**Started:**		**Stopped:**
VIOXX (Other drug)		**Reason:**	
	25.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
ZOTON (Other drug)		**Reason:**	
	60.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Allergies: sulphur, macrodantin. history: coad - smoker, cholecystectomy, hysterectomy, knee arthroscopy.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168293 **Seq:** 1 **Gender:** F
Reported: 10/09/2001 **Weight:**
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

BECLOMETHASONE DIPROPIONATE (Other drug)			**Reason:**	
	400.0 Microgram		Daily	
Batch:	**Started:**		**Stopped:**	
PETHIDINE HYDROCHLORIDE (Other drug)			**Reason:**	
	600.0 Milligram		Daily	
Batch:	**Started:**	19/07/2001	**Stopped:**	20/07/2001
MORPHINE SULPHATE (Other drug)			**Reason:**	
	30.0 Milligram		Daily	
Batch:	**Started:**	20/07/2001	**Stopped:**	20/07/2001

Laboratory Investigations:

Additional Information:

Allergies: sulphur, macrodantin. history: coad - smoker, cholecystectomy, hysterectomy, knee arthroscopy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168334 **Seq:** 1 **Gender:** M
Reported: 20/08/2001 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 27/03/2001 **DOB:** 30/11/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyperhidrosis			Clozaril ceased.

Medicine Details:

ALPRAZOLAM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 16/08/1994 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168345 **Seq:** 1
Reported: 12/09/2001
Hospitalisation:
Onset Date: 15/06/2001
Outcome: Not yet recovered

Gender: F
Weight: 94.00
Age: 45
DOB: 23/12/1955
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gait disturbance Coordination abnormal		Awkward gait and heavy.	Required a visit to doctor. patient on decreasing dose of aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 31/12/1999 **Stopped:** 28/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year. the dose stop date is not necessarily accurate but indicates the drug was stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168635 **Seq:** 1 **Gender:** F
Reported: 20/09/2001 **Weight:**
Hospitalisation: **Age:** 67
Onset Date: 25/06/2001 **DOB:** 17/09/1933
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			Paroxetine ceased. date of recovery 03/07/01.

Medicine Details:

KLIOGEST (Other drug) **Reason:** Essential benign hypertension
0.0
Batch: **Started:** 07/01/1999 **Stopped:**

MONOPLUS 20/12.5 (Other drug) **Reason:** Essential benign hypertension
0.0
Batch: **Started:** 26/09/2000 **Stopped:**

PANAMAX (Other drug) **Reason:**
500.0 Milligram Daily
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168638 **Seq:** 1 **Gender:** U
Reported: 20/09/2001 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 15/09/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Periorbital oedema Lacrimal disorder		Swelling and redness around the eyes.	Required a visit to doctor. aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** 15/09/2001 **Stopped:** 16/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of allergy to sulfur, penicillins.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168665 **Seq:** 1 **Gender:** M
Reported: 24/09/2001 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: 20/09/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Ejaculation failure			Required a visit to doctor.

Medicine Details:

NASONEX AQUEOUS NASAL SPRAY (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

SERETIDE ACCUHALER NOS (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

PRESSIN (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

ACIMAX (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168665 **Seq:** 1
Reported: 24/09/2001
Hospitalisation:
Onset Date: 20/09/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 68Y
DOB:
Causality: Causality possible

Reaction Detai

Medicine Details:

IMOVANE (Other drug)		**Reason:**		
	1.0 Dose Unspecified Daily			
Batch:	**Started:**		**Stopped:**	CONTIN
AROPAX (Suspected)		**Reason:**		
	1.0 Dose Unspecified Daily			
Batch:	**Started:**	S TERM	**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168688 **Seq:** 1 **Gender:** F
Reported: 26/09/2001 **Weight:** 82.00
Hospitalisation: **Age:** 75
Onset Date: **DOB:** 26/11/1925
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Palpitations			Aropax reduced to 10mg daily

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 04/04/2001 **Stopped:** 16/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168710 **Seq:** 1
Reported: 27/09/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/08/2001
Outcome: Recovered

Gender: F
Weight:
Age: 29
DOB: 19/10/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure.	Patient was hospitalised for 2 days. clozaril ceased.

Medicine Details:

ALCOHOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 28/05/2001 **Stopped:** 01/09/2001

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking illicit drugs.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168801 **Seq:** 1
Reported: 01/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 02/09/2001
Outcome: Unknown

Gender: F
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Abdominal pain Feeding disorder neonatal Nervousness		Baby not sleeping well, generally unsettled.	 Baby was hospitalised and put on formula feeding.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Oral application 40.0 Milligram Daily Breast milk transfer

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother takes paroxetine 3pm daily and breastfeeds. baby r.s. 505069 born 2/9/01, developed symptoms, symptoms worse, generally afternoon/night.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 168981 **Seq:** 1
Reported: 05/10/2001
Hospitalisation: Hospitalisation prolonged
Onset Date: 20/08/2001
Outcome: Unknown

Gender: M
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance Paraesthesia Agitation Convulsion		Blurred vision in 1 eye which lasted 5 days. Numbness down the whole right side of his body.	Prolonged hospitalisation.

Medicine Details:

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 20/08/2001 **Stopped:** 20/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 169140 **Seq:** 1
Reported: 15/10/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 92.00
Age: 45
DOB: 23/12/1955
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Neurological symptoms: difficulty	Patient hospitalised for 7 days.

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 17/11/2000 **Stopped:** 09/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also experienced same symptoms on a previous occasion when they briefl y interupted aropax (4 days).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 169290 **Seq:** 1 **Gender:** U
Reported: 22/10/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Micturition disorder			Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 04/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient rechallenged on aropax and same symptoms recurred. patient recovered 10/10/01.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 169359 **Seq:** 1 **Gender:** M
Reported: 24/10/2001 **Weight:** 90.00
Hospitalisation: **Age:** 46
Onset Date: 15/10/2001 **DOB:** 12/05/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Date of recovery 19.10.01.

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** 08/10/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 169473 **Seq:** 1 **Gender:** F
Reported: 22/10/2001 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 01/10/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Dizziness			
Headache			
Hyperhidrosis			
Photophobia			
Visual disturbance			

Medicine Details:

TRAMAL SR (Suspected) **Reason:** Pain
200.0 Milligram Daily
Batch: **Started:** 01/07/2001 **Stopped:** CONTIN

AROPAX (Suspected) **Reason:** Pain
20.0 Milligram Daily
Batch: **Started:** 29/09/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for tramal is not necessarily accurate but indicates the drug was started sometime in the month. next day: took aropax only and no tramadol, felt a lot better. next day: took aropax at 8am and tramadol at 8pm, no reaction. patient has a history of anxiety but she says throughout this episode whe did not feel panicy or particularly anxious.

Report Detail

Case Number: 169486 **Seq:** 1 **Gender:** F
Reported: 29/10/2001 **Weight:** 85.00
Hospitalisation: **Age:** 32
Onset Date: 24/10/2001 **DOB:** 14/01/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations Tachycardia			Treated with iv hydrocortisone, ventolin and phenergan.

Medicine Details:

IMPLANON IMPLANT (Other drug) **Reason:** Contraception
68.0 Milligram 1 time
Batch: **Started:** **Stopped:**

VERACAPS SR (Other drug) **Reason:** Palpitation
160.0 Milligram Daily
Batch: **Started:** **Stopped:**

BRICANYL TURBUHALER (Other drug) **Reason:** Asthma
Inhalation 1.0 Dose Unspecified Alternate weeks Inhalation
Batch: **Started:** **Stopped:**

AMIODARONE HYDROCHLORIDE (Suspected) **Reason:** Palpitation
Injection 0.0 Intravenous
Batch: **Started:** 24/10/2001 **Stopped:** 24/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: asthma, cepression, svt. allergic to iodine and seafood.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 169486 **Seq:** 1
Reported: 29/10/2001
Hospitalisation:
Onset Date: 24/10/2001
Outcome: Recovered

Gender: F
Weight: 85.00
Age: 32
DOB: 14/01/1969
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 12/10/2001 **Stopped:**

Laboratory Investigations:

Additional Information:

Patient history: asthma, cepression, svt. allergic to iodine and seafood.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 169517 **Seq:** 1 **Gender:** M
Reported: 26/10/2001 **Weight:** 70.00
Hospitalisation: **Age:** 30
Onset Date: 04/05/2001 **DOB:** 01/10/1970
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia Anorexia Depression		Loss of energy.	Date of recovery 07/05/01. required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/05/2001 **Stopped:** 05/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Same reaction occurred 6 months ago when patient tried aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 169856 **Seq:** 1 **Gender:** M
Reported: 09/11/2001 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 01/08/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Albuminuria		Proteinuria worsened.	Required a visit to doctor. cyclosporin dose increased.

Medicine Details:

ZOCOR (Other drug) **Reason:** Othr&unspec metabolic diseases
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

NEORAL (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

LISINOPRIL (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for aropax is not necessarily accurate but indicates the d rug was started sometime in the month.

Report Detail

Case Number: 170189 **Seq:** 1 **Gender:** F
Reported: 23/11/2001 **Weight:**
Hospitalisation: **Age:** 57Y
Onset Date: 31/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oliguria Confusional state Headache Hypokalaemia Hyponatraemia Somnolence Thirst		Dificulty passing urine.	Fluid restriction, potassium chloride

Medicine Details:

GLYCERYL TRINITRATE (Other drug) **Reason:** Angina pectoris w/o hyperten
Spray 0.0 Topical
Batch: **Started:** L TERM **Stopped:** CONTIN

THYROXINE SODIUM (Other drug) **Reason:**
Tablet 100.0 Microgram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

AMLODIPINE (Other drug) **Reason:** Angina pectoris w/o hyperten
Capsule 10.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 31/08/2001

SIMVASTATIN (Other drug) **Reason:**
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Sodium = 103 mmol/l, potassium = 2.7 mmol/l

Additional Information:

Report Detail

Case Number: 170189 **Seq:** 1 **Gender:** F
Reported: 23/11/2001 **Weight:**
Hospitalisation: **Age:** 57Y
Onset Date: 31/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Other drug)			**Reason:**		
Tablet	5.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	31/08/2001
AROPAX (Suspected)			**Reason:**		
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**	24/08/2001		**Stopped:**	31/08/2001
IRBESARTAN-HYDROCHLOROTHIAZIDE (Suspected)			**Reason:**		
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	31/08/2001
OXAZEPAM (Suspected)			**Reason:**		
Tablet	300.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	31/08/2001

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 170238 **Seq:** 1 **Gender:** F
Reported: 22/11/2001 **Weight:** 83.00
Hospitalisation: **Age:** 37Y
Onset Date: 29/10/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Acute diarrhoea for 3-4 hours.	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 29/10/2001 **Stopped:** 03/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 170481 **Seq:** 1 **Gender:** F
Reported: 29/11/2001 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 27/12/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tetany Alkalosis Hypocalcaemia Hypokalaemia Hypomagnesaemia Hyponatraemia	Severe	Severe carpopedal spam.	Aropax and lasix ceased.

Medicine Details:

ATENOLOL (Other drug) **Reason:**
0.5 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:**

SLOW-K (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:**

GRANOCOL (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:**

FOLIC ACID (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Calcium Other data Potassium Sodium				Lowered calcium 0.832. total calcium 1.8. Ph - 7.46. K - 2.6. Na - 130.

Additional Information:

Report Detail

Case Number: 170481 **Seq:** 1 **Gender:** F
Reported: 29/11/2001 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 27/12/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

AROPAX (Suspected)			**Reason:**	Depression
	20.0	Milligram	Daily	
Batch:	**Started:**	L TERM	**Stopped:**	27/12/2000
LASIX (Suspected)			**Reason:**	Edema and dropsy
	80.0	Milligram	Daily	
Batch:	**Started:**	L TERM	**Stopped:**	27/12/2000

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 170506 **Seq:** 1
Reported: 29/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2001
Outcome: Recovered

Gender: F
Weight:
Age: 82Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation Dyspnoea Prothrombin level decreased			Required medical attention. date of recovery 8.8.01. patient was hospitalised.

Medicine Details:

MAREVAN (Interaction) **Reason:** Otr&nos disord of heart rhythm
0.0
Batch: **Started:** 04/07/2001 **Stopped:**

NORVASC (Interaction) **Reason:** Essential benign hypertension
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

LIPITOR (Interaction) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

CELEBREX (Interaction) **Reason:** Osteoarthritis
400.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International		10/07/2001	2.2	
	International		06/08/2001	5.1	
	International		07/08/2001	5.0	
	International		08/08/2001	2.6	

Additional Information:

No clear if patient taking vioxx and celebrex concurrently prior to admission.

Report Detail

Case Number: 170506 **Seq:** 1
Reported: 29/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2001
Outcome: Recovered

Gender: F
Weight:
Age: 82Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Interaction)		**Reason:**	Depression
	20.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
VIOXX (Interaction)		**Reason:**	Osteoarthritis
	25.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
ENDONE (Other drug)		**Reason:**	Depression
	5.0 Milligram	As necessary	
Batch:	**Started:**		**Stopped:**
PRAZOSIN HYDROCHLORIDE (Other drug)		**Reason:**	Essential benign hypertension
	4.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

No clear if patient taking vioxx and celebrex concurrently prior to admission.

Report Detail

Case Number: 170506 **Seq:** 1
Reported: 29/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2001
Outcome: Recovered

Gender: F
Weight:
Age: 82Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

KARVEA (Other drug)			**Reason:**	
	300.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
DIGOXIN (Other drug)			**Reason:**	Otr&nos disord of heart rhythm
	125.0	Microgram	Daily	
Batch:	**Started:**			**Stopped:**
CALCITRIOL (Other drug)			**Reason:**	
	2.0	Dose Unspecified	Daily	
Batch:	**Started:**			**Stopped:**
DIAZEPAM (Other drug)			**Reason:**	
	5.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

No clear if patient taking vioxx and celebrex concurrently prior to admission.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 170688 **Seq:** 1 **Gender:** F
Reported: 29/11/2001 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			Therapy changed to sertraline. required medical attention.

Medicine Details:

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 30/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 170950 **Seq:** 1 **Gender:** M
Reported: 10/12/2001 **Weight:** 72.00
Hospitalisation: **Age:** 36
Onset Date: 15/09/2001 **DOB:** 24/07/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia	Severe	From about time of start and for some time	Required a visit to doctor. date of recovery 15.1.01.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 15/09/2001 **Stopped:** 15/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 171160 **Seq:** 1 **Gender:** F
Reported: 17/12/2001 **Weight:** 108.00
Hospitalisation: **Age:** 28Y
Onset Date: 28/06/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased			Diet, exercise etc to no effect. required a visit to doctor. aropax ceased and gradual change over to lovan.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 01/04/2000 **Stopped:** 15/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indiates onset sometime in the month. the dose start date for aropax is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 171197 **Seq:** 1 **Gender:** F
Reported: 13/12/2001 **Weight:** 72.00
Hospitalisation: **Age:** 27
Onset Date: 25/11/2001 **DOB:** 24/03/1974
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Drug withdrawal syndrome			
Hyperhidrosis			
Influenza like illness			
Nausea			Resumed aropax due to severity of withdrawal symptoms
Nightmare			
Paraesthesia			
Photosensitivity reaction			
Thinking abnormal			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/06/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 171380 **Seq:** 1
Reported: 20/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 02/12/2001
Outcome: Recovered

Gender: F
Weight: 80.00
Age: 43
DOB: 07/01/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Asthenia Coordination abnormal Coordination abnormal Muscle twitching		Tingling in arms/hands. Weak legs/dragging.	Patient hospitalised.

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 02/12/2001

AVANZA (Interaction) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** **Stopped:** 03/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction improved when dose of avanza decreased, worsened when dose increased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 171919 **Seq:** 1 **Gender:** F
Reported: 14/01/2002 **Weight:** 56.00
Hospitalisation: **Age:** 21
Onset Date: 08/01/2002 **DOB:** 18/07/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Rash on forearms.	Paroxetine ceased.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 07/01/2002 **Stopped:** 10/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172009 **Seq:** 1 **Gender:** F
Reported: 03/12/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 03/04/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities Neonatal disorder			

Medicine Details:

SODIUM VALPROATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CARBAMAZEPINE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Little boy was born 3/4/00. mother took sodium valproate from the time of conception until delivery at term. at 11 months old he had dysmorphic facial features (mild hypotelorism, epicanthic folds, infra-orbital ridging, upslanting palpable fissures, flat nasal bridge, anteverted nares, smooth philtrum, slightly thin upper lip) and metopic + right lamoidal craniosynosto- sis leading to trigonencephaly and asymmetrical brachycephaly. at this time his development was within the normal range.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172036 **Seq:** 1 **Gender:** F
Reported: 23/01/2002 **Weight:** 65.00
Hospitalisation: **Age:** 26
Onset Date: **DOB:** 20/05/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Migraine			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 10/01/2002 **Stopped:** 10/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Migraine with photosensitivity, dizziness, nausea+++, vomiting and sight disturbances.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172078 **Seq:** 1 **Gender:** M
Reported: 21/01/2002 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 28/10/2001 **DOB:** 05/01/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on aropax since 1998. date of onset is not accurate but indicates onset sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172205 **Seq:** 1
Reported: 29/01/2002
Hospitalisation:
Onset Date: 23/12/2001
Outcome: Not yet recovered

Gender: F
Weight: 69.00
Age: 31
DOB: 17/11/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			Required a visit to doctor. aropax ceased.

Medicine Details:

EPILIM (Other drug) **Reason:** Other&unspecified epilepsy
1.4 Gram Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
1.0 Dose Unspecified Daily
Batch: **Started:** 23/11/2001 **Stopped:** 23/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172216 **Seq:** 1 **Gender:** M
Reported: 29/01/2002 **Weight:**
Hospitalisation: **Age:** 78
Onset Date: 30/11/2001 **DOB:** 27/08/1923
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Hyponatraemia			Fluid restriction. aropax and natrilix ceased.

Medicine Details:

METHOTREXATE (Other drug) **Reason:**
Tablet 2.0 Dose Unspecified Weekly Oral
Batch: **Started:** **Stopped:**

ENALAPRIL MALEATE (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

LOSEC (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

CARTIA (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 172216 **Seq:** 1 **Gender:** M
Reported: 29/01/2002 **Weight:**
Hospitalisation: **Age:** 78
Onset Date: 30/11/2001 **DOB:** 27/08/1923
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOCOR (Other drug)			**Reason:**		
	20.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
AROPAX (Suspected)			**Reason:**	Depression	
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	4D
NATRILIX (Suspected)			**Reason:**	Essential benign hypertension	
Tablet	2.5	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	1Y

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172428 **Seq:** 1 **Gender:** F
Reported: 06/02/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 04/02/2002 **DOB:** 08/04/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			

Medicine Details:

MICROGYNON 50 (Other drug) **Reason:** Contraception
0.0
Batch: **Started:** **Stopped:**

COGENTIN (Other drug) **Reason:**
2.0 Milligram As necessary
Batch: **Started:** **Stopped:**

OXAZEPAM (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 172428 **Seq:** 1 **Gender:** F
Reported: 06/02/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 04/02/2002 **DOB:** 08/04/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected)		**Reason:**	Depression
	20.0 Milligram	2 times	
Batch:	**Started:**		**Stopped:**
ZYPREXA (Suspected)		**Reason:**	Unspecified schizophrenia
	10.0 Milligram	1 time	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172737 **Seq:** 1 **Gender:** M
Reported: 13/02/2002 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 18/03/2001 **DOB:** 02/06/1941
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase in			
Confusional state			
Dyspnoea			
Hyperhidrosis			
Hyperreflexia			
Hypertonia			
Hypokalaemia			
Hyponatraemia			
Muscle twitching			
Neuroleptic malignant syndrome			Hold lithium, olanzapine, paroxetine. strict fluid

Medicine Details:

TEMAZEPAM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

NITRAZEPAM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ASPIRIN (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

FOLIC ACID (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Ck - 8403, ldh - 350
	Electrolytes				Sodium - 116, potassium - 2.6

Additional Information:

Other reaction - rhabdomyolisis.

Report Detail

Case Number: 172737 **Seq:** 1 **Gender:** M
Reported: 13/02/2002 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 18/03/2001 **DOB:** 02/06/1941
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ATORVASTATIN (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
METOPROLOL TARTRATE (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
LITHIUM CARBONATE (Suspected)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	15M
OLANZAPINE (Suspected)			**Reason:**	
	10.0	Milligram Daily		
Batch:	**Started:**		**Stopped:**	15M

Laboratory Investigations:

Additional Information:

Other reaction - rhabdomyolisis.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172737 **Seq:** 1 **Gender:** M
Reported: 13/02/2002 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 18/03/2001 **DOB:** 02/06/1941
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 6M

Laboratory Investigations:

Additional Information:

Other reaction - rhabdomyolisis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 172947 **Seq:** 1
Reported: 20/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 23/01/2001
Outcome: Unrelated death

Gender: M
Weight: 65.00
Age: 75
DOB: 24/09/1925
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Paranoia Psychotic disorder			

Medicine Details:

ASTRIX 100 (Other drug) **Reason:**
0.0
Batch: **Started:** 21/01/2001 **Stopped:**

LIPOBAY (Other drug) **Reason:**
0.0
Batch: **Started:** 21/01/2001 **Stopped:**

AROPAX (Suspected) **Reason:**
0.0
Batch: **Started:** 21/01/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 15/2/01.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173018 **Seq:** 1 **Gender:** F
Reported: 21/02/2002 **Weight:** 86.00
Hospitalisation: **Age:** 43
Onset Date: 26/01/2002 **DOB:** 02/04/1958
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Drug withdrawal syndrome			

Medicine Details:

LIPITOR (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 23/07/1999 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 22/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173058 **Seq:** 1 **Gender:** F
Reported: 21/02/2002 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 02/02/2002 **DOB:** 15/12/1960
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Drug withdrawal syndrome Hyperhidrosis Paraesthesia			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/07/2001 **Stopped:** 02/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The onset date is not necessarily accurate but indicates onset soemtime in the month. the dose start and stop date is not necessarily accurate but indicates the dru g was started and stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173147 **Seq:** 1 **Gender:** F
Reported: 26/02/2002 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: 21/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia Hyponatraemia			Indapamide ceased. iv fluids

Medicine Details:

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:** Essential benign hypertension
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** 20/08/2001 **Stopped:** 25/08/2001

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

PANTOPRAZOLE (Suspected) **Reason:** Other diseases of esophagus
Capsule 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium		25/08/2001	2.8	
	Sodium		25/08/2001	111	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173282 **Seq:** 1 **Gender:** F
Reported: 01/03/2002 **Weight:** 70.00
Hospitalisation: **Age:**
Onset Date: 28/01/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin discolouration		Freckle-like patches on her face.	Required a visit to doctor. changed to efexor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 20/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

Report Detail

Case Number: 173433 **Seq:** 1 **Gender:** M
Reported: 07/03/2002 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 28/11/2001 **DOB:** 31/08/1965
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysphagia Gastrointestinal disorder			Domperidone, omeprazole.

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 14/06/2001 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 20/11/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Barium swallow suggests impaired oesophageal motility.

Additional Information:

Report Detail

Case Number: 173487 **Seq:** 1
Reported: 08/03/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 79
DOB: 17/02/1923
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Aropax ceased. changed to atacand plus to candesartan. patient hospitalised. date of recovery 01/03/2002.

Medicine Details:

ROCALTROL (Other drug) **Reason:**
0.7 Milligram Daily
Batch: **Started:** **Stopped:**

INDERAL (Other drug) **Reason:**
80.0 Milligram Daily
Batch: **Started:** **Stopped:**

LIPEX (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

ATACAND PLUS 16/12.5 (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 25/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		25/02/2002	116	

Additional Information:

Report Detail

Case Number: 173487 **Seq:** 1
Reported: 08/03/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 79
DOB: 17/02/1923
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 18/02/2002 **Stopped:** 25/02/2002

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173633 **Seq:** 1 **Gender:** F
Reported: 08/03/2002 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion Neonatal disorder		Spontaneous abortion at 8 weeks	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/07/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for aropax is not necessarily accurate but indicates aropax was started sometime in the month.

Report Detail

Case Number: 173707 **Seq:** 1 **Gender:** F
Reported: 15/03/2002 **Weight:**
Hospitalisation: **Age:** 87Y
Onset Date: 09/10/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension			

Medicine Details:

COVERSYL PLUS (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 10/10/2001

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 14/10/2001

ATORVASTATIN (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 09/10/2001

FERROUS GLUCONATE (Suspected) **Reason:**
Tablet 325.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 10/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173707 **Seq:** 1
Reported: 15/03/2002
Hospitalisation:
Onset Date: 09/10/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 87Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

TEMAZEPAM (Suspected) **Reason:**

Tablet	10.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 10/10/2001

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173748 **Seq:** 1
Reported: 21/03/2002
Hospitalisation:
Onset Date: 20/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 102.00
Age: 34
DOB: 27/09/1967
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Widespread pruritic, erythematous lisions	Required a visit to doctor, ceased paroxetine.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 20/12/2001 **Stopped:** 19/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173751 **Seq:** 1 **Gender:** U
Reported: 21/03/2002 **Weight:** 100.00
Hospitalisation: **Age:** 59
Onset Date: 01/03/2002 **DOB:** 29/01/1943
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Red rash, raised, slightly itchy,	Required a visit to doctor.

Medicine Details:

PROVERA (Other drug) **Reason:** Menopausal symptoms
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

PREMARIN (Other drug) **Reason:** Menopausal symptoms
1.2 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

BRUFEN (Other drug) **Reason:** Osteoarthritis
1.2 Gram Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** **Stopped:** 04/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 7/3/02.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173774 **Seq:** 1
Reported: 20/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 12/03/2002
Outcome: Recovered

Gender: F
Weight:
Age: 23
DOB: 28/04/1978
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Patient was hospitalised.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected) **Reason:** Otr&unsp vertebrogen pain synd
100.0 Milligram Daily
Batch: **Started:** 02/03/2002 **Stopped:** 13/03/2002

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 02/03/2002 **Stopped:** 13/03/2002

DOTHIEPIN HYDROCHLORIDE (Suspected) **Reason:** Depression
22.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 13/3/02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173775 **Seq:** 1
Reported: 20/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 12/03/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 81Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bleeding time prolonged Purpura		Prolonged bleeding time: 20mins.	Admitted to hospital.

Medicine Details:

LASIX (Other drug) **Reason:** Essential benign hypertension
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

SLOW-K (Other drug) **Reason:** Essential benign hypertension
Tablet 2.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

NORVASC (Other drug) **Reason:** Essential benign hypertension
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

PLAVIX (Suspected) **Reason:**
75.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 15/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				Inr/aptt/platelet count normal.

Additional Information:

Under investigation for vom willebrand disease type 1.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173775 **Seq:** 1
Reported: 20/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 12/03/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 81Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Diabetes mellitus
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 15/03/2002

Laboratory Investigations:

Additional Information:
Under investigation for vom willebrand disease type 1.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173813 **Seq:** 1 **Gender:** F
Reported: 22/03/2002 **Weight:**
Hospitalisation: **Age:** 66
Onset Date: **DOB:** 10/07/1935
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Faecal incontinence			Aropax ceased. required a visit to doctor. patient required a colonoscopy

Medicine Details:

COLOFAC (Other drug) **Reason:** Irritable colon
0.0
Batch: **Started:** **Stopped:**

DUPHALAC (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ALODORM (Other drug) **Reason:** Specific disorders of sleep
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOTON (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient required a colonoscopies.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173813 **Seq:** 1
Reported: 22/03/2002
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 66
DOB: 10/07/1935
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 05/06/2001 **Stopped:**

Laboratory Investigations:

Additional Information:

Patient required a colonoscopies.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173840 **Seq:** 1
Reported: 19/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 10/03/2002
Outcome: Recovered

Gender: F
Weight:
Age: 46
DOB: 03/03/1956
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Generalised seizure or fitting 4hrs after	Patient was hospitalised. a & e review. date of recovery:

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

Batch: **Started:** 10/03/2002 **Stopped:** 10/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173930 **Seq:** 1 **Gender:** F
Reported: 20/03/2002 **Weight:**
Hospitalisation: **Age:** 61Y
Onset Date: 30/10/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Dizziness Dysphagia		Related to urt oedema	

Medicine Details:

BACTRIM (Suspected) **Reason:**
Tablet 2.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 2.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173972 **Seq:** 1 **Gender:** F
Reported: 19/03/2002 **Weight:** 60.00
Hospitalisation: **Age:** 42
Onset Date: 01/03/2002 **DOB:** 23/05/1959
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Interupted sleep, jumped out from sleep.	Required a visit by doctor. date of recovery: 13/3/2002.

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

AVANZA (Interaction) **Reason:** Depression
30.0 Milligram Daily
Batch: **Started:** 27/02/2002 **Stopped:** 08/03/2002

CAPADEX (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** 01/02/2002 **Stopped:** CONTIN

PREMARIN (Other drug) **Reason:**
625.0 Microgram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 173972 **Seq:** 1 **Gender:** F
Reported: 19/03/2002 **Weight:** 60.00
Hospitalisation: **Age:** 42
Onset Date: 01/03/2002 **DOB:** 23/05/1959
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

URAL (Other drug)		**Reason:**		
	3.0 Dose Unspecified	Daily		
Batch:	**Started:** 01/02/2002		**Stopped:**	CONTIN
ATIVAN (Other drug)		**Reason:**		
	4.5 Milligram	Daily		
Batch:	**Started:** 25/02/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 174069 **Seq:** 1
Reported: 27/03/2002
Hospitalisation:
Onset Date: 28/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 90.00
Age: 43
DOB: 24/01/1959
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			Required a visit to doctor.

Medicine Details:

PAXTINE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/10/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates the drug was started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 174191 **Seq:** 1
Reported: 04/04/2002
Hospitalisation:
Onset Date: 23/03/2002
Outcome: Not yet recovered

Gender: M
Weight: 72.00
Age: A4
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Hyperhidrosis Nausea Tremor Vomiting			Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

20.0 Milligram Daily

Batch: **Started:** 29/01/2002 **Stopped:** 23/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Long history of depression but 1st attempt at treatment.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 174259 **Seq:** 1 **Gender:** F
Reported: 08/04/2002 **Weight:** 55.00
Hospitalisation: **Age:** 43Y
Onset Date: 07/03/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Leukopenia Weight increased			Date of recovery 04/04/02

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 18/10/2001 **Stopped:** 12/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 174516 **Seq:** 1 **Gender:** F
Reported: 15/04/2002 **Weight:** 100.00
Hospitalisation: **Age:** 38
Onset Date: 05/04/2002 **DOB:** 25/02/1964
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 04/04/2002 **Stopped:** 06/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 174877 **Seq:** 1 **Gender:** M
Reported: 22/04/2002 **Weight:** 87.00
Hospitalisation: **Age:** 29
Onset Date: 11/04/2002 **DOB:** 12/04/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Pruritus		Skin rash on legs.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 11/04/2002 **Stopped:** 18/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to penicillin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175188 **Seq:** 1 **Gender:** F
Reported: 24/04/2002 **Weight:**
Hospitalisation: **Age:** 19Y
Onset Date: 03/04/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination Mania Psychotic disorder			Treated with haloperidol and epilim. patient was hospitalised

Medicine Details:

HERRON HL676 HERBAL MEDICINE ST JOHN'S WORT (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ECSTASY (M.D.M.A.) (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 14/03/2002 **Stopped:** 03/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Uni student, caught urti and became depressed and commenced smoking and using ecstacy unusual behaviour for her.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175200 **Seq:** 1
Reported: 06/05/2002
Hospitalisation:
Onset Date: 28/03/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 47
DOB: 09/03/1955
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Headache Hyperhidrosis Paraesthesia Purpura Rash erythematous Vertigo			Zocor ceased. required a visit to doctor.

Medicine Details:

ZOCOR (Interaction) **Reason:** Othr&unspec metabolic diseases
20.0 Milligram Daily
Batch: **Started:** 07/03/2002 **Stopped:** 29/04/2002

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Obsessive compulsive neurosis
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

LOSEC (Other drug) **Reason:** Peptic ulcer nos w/o ment perf
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175223 **Seq:** 1 **Gender:** F
Reported: 07/05/2002 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 28/12/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Chills			
Headache			
Hyperhidrosis			
Insomnia			Treated with panadeine forte, valium, dolased and nurofen.
Muscle twitching			
Myalgia			
Pyrexia			
Somnolence			
Weight decreased			

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 01/10/2000 **Stopped:** 04/03/2002

TRAMAL (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 24/11/2001 **Stopped:** 04/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. patient also suffered lethargy, nausea and fatigue. the dose start date for aropax is not necessarily accurate but indicates the drug was strted sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175383 **Seq:** 1
Reported: 13/05/2002
Hospitalisation:
Onset Date: 18/04/2002
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 41
DOB: 14/02/1961
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Bruises to legs.	Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** 01/02/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175448 **Seq:** 1 **Gender:** F
Reported: 16/05/2002 **Weight:** 65.00
Hospitalisation: **Age:** 52Y
Onset Date: 28/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Drug withdrawal syndrome Dizziness Hyperhidrosis Tremor		Couldn't move head. Withdrawal symptoms for 1 month.	Date of recovery january 2002. aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/01/1995 **Stopped:** 28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for aropax is not accurate but indicates the drug was started sometime in the year. the dose stop date dor aropax is not necessarily accurate but indicates the drug was stopped sometime in the month. the withdrawal symptoms were severe enough to prevent her from driving for 2 weeks.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175617 **Seq:** 1 **Gender:** F
Reported: 21/05/2002 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 28/11/2001 **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchospasm			Aropax ceased.

Medicine Details:

FELDENE (Other drug) **Reason:** Synovitis,bursitis&tenosynovit
Capsule 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LEVLEN ED (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Synovitis,bursitis&tenosynovit
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/10/2001 **Stopped:** 28/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates oncet sometime in the month. the dose start date for aropax is not necessarily accurate but indicates the drug was started sometime in the month. the dose stop date is not necessarily accurate but indicates the drug was stopped sometime in the month. past history of childhood asthma but had been symptom free for years.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175667 **Seq:** 1 **Gender:** F
Reported: 24/05/2002 **Weight:** 80.00
Hospitalisation: **Age:** 19
Onset Date: 28/02/1997 **DOB:** 12/10/1977
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Visual disturbance			Aropax recommenced.

Medicine Details:

AROPAX (Suspected) **Reason:** Obsessive compulsive neurosis
2.0 Dose Unspecified Daily
Batch: **Started:** 01/01/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

When stopping aropax after 4 days, which patient has done several times, eyes jumping from position to position (not spasming). when she turns to look she sees the picture in frames - not flowing, makes her dizzy as well. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for aropax is not accurate but indicates aropax was started sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175713 **Seq:** 1 **Gender:** F
Reported: 28/05/2002 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 28/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Convulsion Muscle twitching Nightmare Psychotic disorder		Out of body experience.	Required a visit to doctor. treated with diazepam.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 01/11/2001 **Stopped:** 28/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start and stop dates for aropax are not necessarily accurate but indictes the drug was started and stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175714 **Seq:** 1 **Gender:** F
Reported: 28/05/2002 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 28/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability Drug withdrawal syndrome			Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** 01/11/2001 **Stopped:** 28/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start and stop dates for aropax are not necessarily accurate but indicates the drug was started and stopped sometime in the month. weaned herself off, reducing by 1/4 tablet. withdrawal associated with mood changes and depression.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 175810 **Seq:** 1 **Gender:** F
Reported: 19/05/2002 **Weight:** 60.00
Hospitalisation: **Age:** 36
Onset Date: 19/05/2002 **DOB:** 10/12/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Anxiety Confusional state Dizziness Paraesthesia			

Medicine Details:

ZOMIG (Other drug) **Reason:**
2.5 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 16/05/2002 **Stopped:** 20/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176076 **Seq:** 1
Reported: 22/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 02/02/2000
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 64
DOB: 20/10/1935
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal carcinoma Diarrhoea	Caused or prolonged inpatient hospitalisation	Gastrointestinal tract cancer/early stage bowel cancer	

Medicine Details:

ARAVA (Suspected) **Reason:** Other rheumatoid arthritis
0.0
Batch: **Started:** 01/02/2000 **Stopped:** 20/03/2002

SULFASALAZINE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PREDNISONE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

PREMARIN (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Other data				Colonoscopy revealed early stage bowel cancer.

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176076 **Seq:** 1
Reported: 22/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 02/02/2000
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 64
DOB: 20/10/1935
Causality: Causality possible

Reaction Detail

Medicine Details:

TENORMIN (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**
AROPAX (Suspected)		**Reason:**
	0.0	
Batch:	**Started:**	**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176335 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: 28/11/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Easy bruising.	Paxtine ceased and recovered within 4-5 days.

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:**
2.0 Dose Unspecified As necessary
Batch: **Started:** L TERM **Stopped:** CONTIN

ACIMAX (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

PAXTINE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/11/2001 **Stopped:** 3W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176427 **Seq:** 1 **Gender:** F
Reported: 11/06/2002 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: 10/05/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Headache Rash		Heaviness in legs.	Date of recovery 16.5.02.

Medicine Details:

TRAMAL (Interaction) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

AROPAX (Interaction) **Reason:** Depression
0.4 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176438 **Seq:** 1 **Gender:** F
Reported: 19/06/2002 **Weight:** 60.00
Hospitalisation: **Age:** 32
Onset Date: 12/06/2002 **DOB:** 28/04/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia	Severe	Severe orofacial and skeletal muscle	Required a visit to doctor. treated with cogentin.

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 11/06/2002 **Stopped:** 12/06/2002

CAMPRAL (Interaction) **Reason:** Alcoholic addiction
333.0 Milligram Daily
Batch: **Started:** 12/06/2002 **Stopped:** 12/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 12/6/02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176557 **Seq:** 1 **Gender:** M
Reported: 26/06/2002 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 18/05/2002 **DOB:** 16/06/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Euphoric mood Hallucination			Self treated with vitamin b. required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 22/11/2001 **Stopped:** 16/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176632 **Seq:** 1 **Gender:** F
Reported: 24/06/2002 **Weight:** 70.00
Hospitalisation: **Age:** 50
Onset Date: 30/06/2000 **DOB:** 20/07/1949
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psoriasis		Lareup of pre-existing childhoot psoriasis.	Treated with puva. required a visit to doctor. date of recovery

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
10.0 Milligram Daily
Batch: **Started:** 24/06/2000 **Stopped:** 08/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had been on meclobemide, ceased 2-3 days prior to starting paroxetine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176633 **Seq:** 1
Reported: 24/06/2002
Hospitalisation:
Onset Date: 19/04/2001
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 37
DOB: 21/01/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psoriasis		Outbreak of extensive psoriasis.	Required a visit to doctor.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 12/04/2001 **Stopped:** 15/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176648 **Seq:** 1 **Gender:** F
Reported: 26/06/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 22/05/2002 **DOB:** 21/12/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams			
Fall			
Fatigue			
Insomnia			
Oedema			
Psychotic disorder			Patient was treated with valium

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 21/11/2001 **Stopped:** 28/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date is not necessarily accurate but indicates that the drug was stopped sometime in the month. patient woke one morning to discover herself on the floor of her bedroom with a bitten tongue, cut face and bump on head.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 176732 **Seq:** 1 **Gender:** M
Reported: 28/06/2002 **Weight:**
Hospitalisation: **Age:** 80
Onset Date: 31/12/1996 **DOB:** 09/09/1916
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pneumonia Pulmonary fibrosis			

Medicine Details:

LOSEC (Suspected)		**Reason:**	
Oral application	0.0		Oral
Batch:	**Started:**		**Stopped:**
AROPAX (Suspected)		**Reason:**	Depression
Oral application	0.0		Oral
Batch:	**Started:**		**Stopped:**
VOLTAREN (Suspected)		**Reason:**	
Tablet	0.0	Daily	Oral
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year. no autopsy was performed. report 177457 is a duplicate of this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177080 **Seq:** 1 **Gender:** M
Reported: 15/07/2002 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 30/05/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Dizziness Myalgia Tremor		Burning sensation in various parts of his	

Medicine Details:

LOSEC (Other drug) **Reason:** Gastritis&duodenitis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 10/05/2002 **Stopped:**

AROPAX (Suspected) **Reason:** Obsessive compulsive neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 28/05/2002 **Stopped:** 11/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177097 **Seq:** 1 **Gender:** M
Reported: 15/07/2002 **Weight:** 77.00
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 05/12/1972
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Vertigo			Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Obsessive compulsive neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 15/03/2002 **Stopped:** 09/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177409 **Seq:** 1 **Gender:** M
Reported: 23/07/2002 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 28/05/2002 **DOB:** 01/07/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life	2 separate episodes of loss of mem/con for	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 08/05/2002 **Stopped:** 27/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the patient commenced alternate ssri with milder but similar episodes also experienced.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177473 **Seq:** 1 **Gender:** M
Reported: 26/07/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Inability to descriminate colour	As dose of aropax increases from 20-60 mg patient experiences symptoms which resolves as dose decreased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
60.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177562 **Seq:** 1 **Gender:** F
Reported: 31/07/2002 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: 16/07/2002 **DOB:** 19/01/1958
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Tingling in arms and chest	Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 13/07/2002 **Stopped:** 16/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177563 **Seq:** 1 **Gender:** F
Reported: 31/07/2002 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: 28/07/2002 **DOB:** 19/01/1958
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Anxiety Depression Fatigue Somnolence		Feeling spaced out.	Required a visit ot doctor. reduced dosage to 10mg from

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 28/07/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177718 **Seq:** 1 **Gender:** M
Reported: 05/08/2002 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 24/07/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response unexpecte			Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/09/2001 **Stopped:** 15/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Therapeutic effect unexpected: a history of chronic asthma which 'disappeared when patient was taking aropax'.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177719 **Seq:** 1 **Gender:** M
Reported: 05/08/2002 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 24/07/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia			Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/09/2001 **Stopped:** 15/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Memory loss: with vague patches of recollection and cannot clearly remember a period of eight weeks.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177811 **Seq:** 1
Reported: 07/08/2002
Hospitalisation:
Onset Date: 08/07/2002
Outcome: Not yet recovered

Gender: M
Weight: 78.00
Age: 63
DOB: 23/03/1939
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Erectile dysfunction Pruritus		Bilateral lesions 5-20mm diameter.	

Medicine Details:

AROPAX (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** 25/06/2002 **Stopped:** 29/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 177879 **Seq:** 1 **Gender:** F
Reported: 08/08/2002 **Weight:**
Hospitalisation: **Age:** 58
Onset Date: 04/08/2002 **DOB:** 22/08/1943
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Confusional state Hyponatraemia		Bizarre behaviour.	 Patient was hospitalised

Medicine Details:

TEGRETOL CR (Interaction) **Reason:** Other&unspecified epilepsy
400.0 Milligram Daily
Batch: **Started:** 01/01/1990 **Stopped:** 05/08/2002

AROPAX (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 01/07/2002 **Stopped:** 05/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Na 118

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 178005 **Seq:** 1
Reported: 12/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 27/06/2002
Outcome: Recovered

Gender: F
Weight:
Age: 87
DOB: 04/04/1915
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Orthostatic hypotension Syncope Vertigo			Patient was hospitalised, rivastigmine and paroxetine were ceased

Medicine Details:

PARACETAMOL (Other drug) **Reason:**
0.0 As necessary
Batch: **Started:** **Stopped:** CONTIN

CELEBREX (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram As necessary Oral
Batch: **Started:** 01/02/2000 **Stopped:** 01/07/2000

RIVASTIGMINE (Suspected) **Reason:** Presenile dementia
Capsule 3.0 Milligram Daily Oral
Batch: **Started:** 01/03/2001 **Stopped:** 28/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Multiple similar episodes. the dose start dates are not necessarily accurate but indicates rivastigmine and paroxetine were started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 178145 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:** 43.00
Hospitalisation: **Age:** 39Y
Onset Date: 14/08/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation			

Medicine Details:

PREDNISONE (Other drug) **Reason:** Otr&unsp difuse connec tis dis

Oral application 8.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** CONTIN

AROPAX (Suspected) **Reason:**

Tablet 0.0 Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is the first of two sequences: 178146 seq 2.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 178268 **Seq:** 1 **Gender:** F
Reported: 26/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Faecal incontinence			Aropax ceased.

Medicine Details:

ORAL CONTRACEPTIVE NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 178288 **Seq:** 1 **Gender:** F
Reported: 15/07/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion		Lost the foetus around 7 weeks of	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient, in the past, had a healthy baby girl while on aropax 20-40mg daily, who is now 2 years of age.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 178346 **Seq:** 1 **Gender:** M
Reported: 21/08/2002 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Dysarthria	 Severe		Aropax discontinued.

Medicine Details:

AROPAX (Suspected) **Reason:** Stammering and stuttering
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 01/12/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax was discontinued between 18th and 25th of april. aropax was restarted at a daily dose of 10mg and 5mg. the dose start date for the drug aropax is not necessarily accurate but indicates the drug was started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 178403 **Seq:** 1 **Gender:** F
Reported: 23/08/2002 **Weight:** 65.00
Hospitalisation: **Age:** 32
Onset Date: 03/08/2002 **DOB:** 23/01/1970
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise			Cessation of drug therapy.

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0

Batch: **Started:** **Stopped:** 3D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

178403 is the sequence of 178404.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 179235 **Seq:** 1 **Gender:** F
Reported: 30/09/2002 **Weight:** 69.00
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 15/02/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability			
Agitation			
Dizziness			
Drug withdrawal syndrome			Required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
5.5 Dose Unspecified Daily
Batch: **Started:** 01/01/2002 **Stopped:** 28/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start and stop dates are not necessarily accurate but indicates aropax was started and stopped sometime in the month.

Report Detail

Case Number: 179292 **Seq:** 1 **Gender:** F
Reported: 20/09/2002 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: 15/01/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			Paroxetine was ceased.

Medicine Details:

SORBITOL (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** CONTIN

COLOXYL WITH SENNA (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

METOCLOPRAMIDE HYDROCHLORIDE (Other drug) **Reason:**
Tablet 10.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:** CONTIN

DIAZEPAM (Other drug) **Reason:**
Tablet 5.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Main medical problems - bilateral optic neuritis, possible cerebral vasculitis,? miller fisher/guillian barre syndrome, altered consciousness,? seizures. taking paroxetine for anxiety. hallucinations resolved when paroxetine ceased.

Report Detail

Case Number: 179292 **Seq:** 1 **Gender:** F
Reported: 20/09/2002 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: 15/01/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

CAPADEX (Other drug)			**Reason:**			
Capsule	6.0	Dose Unspecified	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
ASPIRIN (Other drug)			**Reason:**			
Tablet	150.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
POTASSIUM NOS (Other drug)			**Reason:**			
Tablet	1.2	Gram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
SODIUM VALPROATE (Other drug)			**Reason:**	Convulsions		
Tablet	400.0	Milligram	Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN

Laboratory Investigations:

Additional Information:

Main medical problems - bilateral optic neuritis, possible cerebral vasculitis,? miller fisher/guillian barre syndrome, altered consciousness,? seizures. taking paroxetine for anxiety. hallucinations resolved when paroxetine ceased.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 179292 **Seq:** 1 **Gender:** F
Reported: 20/09/2002 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: 15/01/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis

Tablet	20.0	Milligram	Daily	Oral

Batch: **Started:** 12/01/2002 **Stopped:** 15/01/2002

Laboratory Investigations:

Additional Information:

Main medical problems - bilateral optic neuritis, possible cerebral vasculitis,? miller fisher/guillian barre syndrome, altered consciousness,? seizures. taking paroxetine for anxiety. hallucinations resolved when paroxetine ceased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 179506 **Seq:** 1
Reported: 01/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 26/08/2002
Outcome: Recovered

Gender: F
Weight:
Age: 72
DOB: 22/04/1930
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia Hyponatraemia Inappropriate antidiuretic hormon			Cessation of paroxetine. rehydration with saline-potassium chloride infusion, admitted to hospital

Medicine Details:

ALENDRONATE SODIUM (Other drug) **Reason:** Other diseases of bone
Oral application 70.0 Milligram Weekly Oral
Batch: **Started:** **Stopped:**

ATENOLOL (Other drug) **Reason:** Essential benign hypertension
Oral application 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TAMOXIFEN CITRATE (Other drug) **Reason:** Malignant neoplasm of breast
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SLOW-K (Other drug) **Reason:** Alkalosis
Oral application 3.6 Gram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium Sodium				Hypokalaemia (k 1.9) increased urine osmolatily. Na = 110 decreased plasma osmolality.

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 179506 **Seq:** 1
Reported: 01/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 26/08/2002
Outcome: Recovered

Gender: F
Weight:
Age: 72
DOB: 22/04/1930
Causality: Causality possible

Reaction Detail

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 0.0 Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 179632 **Seq:** 1 **Gender:** M
Reported: 03/10/2002 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 14/08/2002 **DOB:** 24/04/1954
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia Ejaculation failure Nocturia		Worsening dyspepsia.	Required a visit to doctor. patient recovered 26/9/02.

Medicine Details:

TAZAC (Other drug) **Reason:**
150.0 Milligram As necessary
Batch: **Started:** 01/08/2001 **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 09/08/2002 **Stopped:** 16/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 179702 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:** 90.00
Hospitalisation: **Age:** 39
Onset Date: 27/05/1996 **DOB:** 17/01/1957
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension Dizziness	Required Visit to Doctor	Bp 160/110	Ceased aropax.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 23/04/1996 **Stopped:** 27/05/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 180136 **Seq:** 1
Reported: 23/10/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age:
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Meningism Drug withdrawal syndrome		A variety of symptoms suggestive of	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Microbiology				Lumber puncture normal

Additional Information:

Report Detail

Case Number: 180215 **Seq:** 1 **Gender:** F
Reported: 29/10/2002 **Weight:** 65.00
Hospitalisation: **Age:** 79
Onset Date: 20/01/1999 **DOB:** 08/11/1919
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, auditory		Noises in both ears, music and voices singing, also tinnitus	
Tinnitus		Noises in both ears, music and voices singing, also tinnitus	

Medicine Details:

CAPTOPRIL (Other drug) **Reason:**
12.5 Milligram Daily
Batch: **Started:** **Stopped:**

OROXINE (Other drug) **Reason:**
50.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

LOSEC (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

PROVERA (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

180215 is the sequence of 180216.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 180215 **Seq:** 1 **Gender:** F
Reported: 29/10/2002 **Weight:** 65.00
Hospitalisation: **Age:** 79
Onset Date: 20/01/1999 **DOB:** 08/11/1919
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

CLIMARA (Other drug)			**Reason:**		
	50.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	
LIPEX (Other drug)			**Reason:**		
	20.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	
AROPAX (Suspected)			**Reason:**		
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**	10/06/1998		**Stopped:**	28/02/1999

Laboratory Investigations:

Additional Information:
180215 is the sequence of 180216.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 180504 **Seq:** 1
Reported: 08/11/2002
Hospitalisation:
Onset Date: 28/11/1999
Outcome: Not yet recovered

Gender: F
Weight: 65.00
Age: 28Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Increased appetite		Total weight gain 25kg over 18 months.	Cessation of aropex. patient began therapy with zoloft (oct 2001). patient herself attemped to reduced aropex dose. required a visit to doctor.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Oral application 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/07/1999 **Stopped:** 28/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The report - 180504 is a sequence to 180505. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start and stop date for the drug aropax is not necessarily accurate but indicates the drug was started and stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 180706 **Seq:** 1 **Gender:** U
Reported: 17/12/2002 **Weight:** 89.00
Hospitalisation: **Age:** 51
Onset Date: 17/09/2002 **DOB:** 18/05/1951
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia		Severe anorexia causing 9 kg weight loss in approx 1 month	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 17/09/2002 **Stopped:** 01/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 180764 **Seq:** 1 **Gender:** M
Reported: 18/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 72
Onset Date: 15/04/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue	Required Visit to Doctor	Extreme fatigue, sweating, palpitations, especially over the last month, worse in last few days.	Nil.
Hyperhidrosis	Required Visit to Doctor		
Palpitations	Required Visit to Doctor		
Serotonin syndrome	Required Visit to Doctor		

Medicine Details:

ENDEP (Interaction) **Reason:** Otr&unsp forms neuralg&neurit
Tablet 50.0 Milligram As necessary Oral
Batch: **Started:** L TERM **Stopped:**

TRAMAL SR (Interaction) **Reason:** Osteoarthritis
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 03/12/2001 **Stopped:**

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/12/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 180843 **Seq:** 1 **Gender:** F
Reported: 19/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 47
Onset Date: 10/07/2002 **DOB:** 19/03/1955
Outcome: Recovered 10/08/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Electric shocks through body from feet and up to top of head	Required a visit to doctor. Decreased and withdrew Paroxetine with no response. Switched to MS

Medicine Details:

EPILIM (Other drug) **Reason:** Convulsions
1.8 Gram Daily
Batch: **Started:** **Stopped:**

TRAMAL SR (Suspected) **Reason:** Pain
400.0 Milligram Daily Oral
Batch: **Started:** 08/07/2002 **Stopped:** 08/08/2002

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 01/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 181063 **Seq:** 1 **Gender:** F
Reported: 03/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 64
Onset Date: 27/04/2002 **DOB:** 16/10/1937
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Shock Hypoglycaemia Hyponatraemia Nausea		Hypovolaemic shock, hypoglycaemia, poor oral intake	Paroxetine ceased.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 27/04/2002 **Stopped:** 09/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/01/2003	Serum osmolality				
03/01/2003	Sodium		27/04/2002	126	
03/01/2003	Sodium		27/04/2002	269	
03/01/2003	Urine Sodium		27/04/2002	94	
03/01/2003	Urine osmolality		27/04/2002	357	

Additional Information:

Patient also taking Prednisolone, Ramipril, Calcitriol, Ventolin, Atrovent, Premarin, Panadol, Salbutamol, Atrovent, Metoclopramide, Folic acid.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 181089 **Seq:** 1 **Gender:** F
Reported: 03/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neonatal hypoxia		Neonatal hypoxia after grade 4 haemorrhage placenta previa	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

181089 (baby) is linked to 181090 (mother).

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 181090 **Seq:** 1 **Gender:** F
Reported: 03/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Antepartum haemorrhage		Mother suffered Grade 4 haemorrhage placenta previa. Due to hypoxia the child suffered delayed brain damage.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

181090 is linked to 181089.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 181639 **Seq:** 1 **Gender:** F
Reported: 15/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: 13/12/2002 **DOB:** 27/01/1951
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life	Hypernatraemia, dizziness, headache,	Phenytoin, 5ml of 34mmol/10ml Nacl given plus N/s, Ng feeds started to increase oral Na input. Medications ceased
Convulsion	Life		
Dizziness	Life		
Headache	Life		

Medicine Details:

ATORVASTATIN (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 16/12/2002

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 10/12/2002 **Stopped:** 16/12/2002

IRBESARTAN (Suspected) **Reason:** Essential benign hypertension
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 16/12/2002

THYROXINE SODIUM (Suspected) **Reason:** Myxedema
Tablet 50.0 Microgram Daily Oral
Batch: **Started:** **Stopped:** 16/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/01/2003	Sodium		16/12/2002	<113	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 181920 **Seq:** 1 **Gender:** F
Reported: 22/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 25/12/2002 **DOB:** 15/03/1932
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia	Natrilix and Aropax ceased, given salt orally.

Medicine Details:

ODRIK (Other drug) **Reason:** Essential benign hypertension
Capsule 1.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

GENORAL (Other drug) **Reason:** Menopausal symptoms
1.3 Milligram Daily
Batch: **Started:** **Stopped:**

NATRILIX SR (Suspected) **Reason:** Essential benign hypertension
Tablet 1.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** 24/12/2002

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 25/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2003	Sodium		25/12/2002	118	
22/01/2003	Sodium		27/12/2002	109	
22/01/2003	Sodium		30/12/2002	124	

Additional Information:

Patient was also taking Serepax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182327 **Seq:** 1 **Gender:** F
Reported: 04/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 03/10/2002 **DOB:** 10/03/1932
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome, difficulty walking, coordination, psychomotor retardation, confusion, difficulty following nstructions, anxiety/aggitation, sleep disturbances, loss of weight, CPK increased.,	MRI Brain performed. Routine U &Es performed and CK. Aropax ceased and patient observed.
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CANDESARTAN-HYDROCHLOROTHIAZIDE (Other drug) **Reason:**
Tablet 16.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/02/2003	Creatine				

Additional Information:

Patient was also taking metoprolol, Pantoprazole, Flunitrazepam, Thyroxine, Simvastatin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182327 **Seq:** 1 **Gender:** F
Reported: 04/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 03/10/2002 **DOB:** 10/03/1932
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase in	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CANDESARTAN-HYDROCHLOROTHIAZIDE (Other drug) **Reason:**
Tablet 16.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Additional Information:

Patient was also taking metoprolol, Pantoprazole, Flunitrazepam, Thyroxine, Simvastatin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182327 **Seq:** 1 **Gender:** F
Reported: 04/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 03/10/2002 **DOB:** 10/03/1932
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Caused or prolonged inpatient hospitalisation		
Gait disturbance	Caused or prolonged inpatient hospitalisation		
Sleep disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CANDESARTAN-HYDROCHLOROTHIAZIDE (Other drug) **Reason:**
Tablet 16.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Additional Information:
Patient was also taking metoprolol, Pantoprazole, Flunitrazepam, Thyroxine, Simvastatin.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182327 **Seq:** 1 **Gender:** F
Reported: 04/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 03/10/2002 **DOB:** 10/03/1932
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CANDESARTAN-HYDROCHLOROTHIAZIDE (Other drug) **Reason:**
Tablet 16.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Additional Information:

Patient was also taking metoprolol, Pantoprazole, Flunitrazepam, Thyroxine, Simvastatin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182434 **Seq:** 1 **Gender:** F
Reported: 06/02/2003 **Weight:** 49.00
Hospitalisation: **Age:** 43
Onset Date: 24/12/2002 **DOB:** 05/11/1959
Outcome: Recovered 15/01/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Visit to Doctor	Generalised pruritic maculopapular rash	Did not respond to antihistamines or steroids (topical and oral). Aropax ceased
Rash maculo-papular	Required Visit to Doctor	Generalised pruritic maculopapular rash	Did not respond to antihistamines or steroids (topical and oral). Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 22/04/2002 **Stopped:** 11/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182512 **Seq:** 1 **Gender:** F
Reported: 07/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 01/01/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypomagnesaemia		Decreased Mg (FBC)	
Yawning		Frequent yawning	
Hypertonia neonatal		Increased muscle tone	
Irritability		Irritability	
Convulsion neonatal		Jittery, probably seizures	
Lethargy		Lethargic	
Fever neonatal		Mildly febrile (37) persistent	
Feeding disorder neonatal		Poor suck, poor feeding	
Drug withdrawal syndrome neona			Pyridoxine 100mg IV stat then maintenance dose phenobarbitone
Vomiting neonatal			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby born 01/01/2003 - poor suck/poor feeding, mildly febrile (37) persistent, irritability, increased muscle tone, jittery, probably seizures, vomiting, frequent yawning, decreased Mg (FBC), lethargic. Aropax taken by mother during pregnancy.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182587 **Seq:** 1 **Gender:** F
Reported: 10/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: 05/09/2002 **DOB:** 28/03/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Patient experienced medically significant panic attacks, anxiety attacks and felt anxious	
Panic attack		Patient experienced medically significant panic attacks, anxiety attacks and felt anxious	

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
Oral application Dose Unspecified Oral
Batch: **Started:** **Stopped:**

XENICAL (Interaction) **Reason:** Obesity othr than endoc origin
Capsule 120.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history - panic attacks-meddra 5.1 and obesity-meddra 5.1

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182678 **Seq:** 1 **Gender:** M
Reported: 11/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 20/01/2003 **DOB:** 18/04/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria	Required Visit to Doctor	Itchy urticarial eruption all over body	oral steroids, antihistamines.

Medicine Details:

AROPAX (Suspected) **Reason:** Smoker
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 09/01/2003 **Stopped:** 23/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 182786 **Seq:** 1 **Gender:** M
Reported: 12/02/2003 **Weight:** 75.00
Hospitalisation: Admitted to hospital **Age:** 62
Onset Date: 23/01/2003 **DOB:** 11/04/1940
Outcome: Recovered 29/01/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Serotonin syndrome.	All drugs ceased. Chlorpromazine 50mg tds.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 25/01/2003

TRAMAL SR (Interaction) **Reason:** Pain
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 19/01/2003 **Stopped:** 25/01/2003

DIAZEPAM (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 19/01/2003 **Stopped:** 25/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 183363 **Seq:** 1 **Gender:** F
Reported: 30/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion neonatal		The neonate suffered 3 seizures several days after birth.	
Drug withdrawal syndrome neona		The neonate's mother was pregnant whilst taking Aropax.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 183569 **Seq:** 1 **Gender:** M
Reported: 28/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Agitation Anxiety Hyperreflexia Tachycardia Tremor		Serotonin syndrome, drug interaction NOS and heart rate 110-120bpm.	Cyproheptadine 8mg and then 4mg every 8 hours.

Medicine Details:

AROPAX (Interaction) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

DESIPRAMINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 183754 **Seq:** 1
Reported: 06/03/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Pneumonia, acute cardiac failure and pulmonary oedema.	
Cardiac failure	Caused or prolonged inpatient hospitalisation		
Pulmonary oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:** Obsessive compulsive neurosis

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: existing bronchiectasis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 183773 **Seq:** 1 **Gender:** F
Reported: 06/03/2003 **Weight:** 80.00
Hospitalisation: **Age:** 32
Onset Date: 18/02/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Hypertension Tachycardia		Serotonin reaction, tachycardia and	Aropax decreased.

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 10/02/2003 **Stopped:** 03/03/2003

BUPRENORPHINE HYDROCHLORIDE (Interaction) **Reason:**
4.0 Milligram Daily
Batch: **Started:** 18/02/2003 **Stopped:** Contin

PETHIDINE HYDROCHLORIDE (Other drug) **Reason:**
Daily
Batch: **Started:** 01/12/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 183884 **Seq:** 1 **Gender:** M
Reported: 10/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 04/02/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Dizziness		Sweating and dizziness	Aropax ceased.

Medicine Details:

ALCOHOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184002 **Seq:** 1 **Gender:** M
Reported: 13/03/2003 **Weight:** 56.00
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 05/02/2003 **DOB:** 18/07/1966
Outcome: Recovered 19/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonergic syndrome with sweatness ++ spasms of jaw and neck muscles increased tone, clonus at ankles, increased reflexes	Ceased paroxetine.
Clonus	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DOXYCYCLINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 04/02/2003 **Stopped:** 17/02/2003

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 04/02/2003 **Stopped:** 17/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184002 **Seq:** 1 **Gender:** M
Reported: 13/03/2003 **Weight:** 56.00
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 05/02/2003 **DOB:** 18/07/1966
Outcome: Recovered 19/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperreflexia	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Muscle spasms	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DOXYCYCLINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 04/02/2003 **Stopped:** 17/02/2003

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 04/02/2003 **Stopped:** 17/02/2003

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184015 **Seq:** 1
Reported: 14/03/2003
Hospitalisation: Admitted to hospital
Onset Date: 13/01/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 80
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Chest pains	Ceased Aropax, Zoloft therapy was initiated.

Medicine Details:

IMDUR (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
XANAX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
AROPAX (Suspected)		**Reason:**	Depression
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also takingbeta blocker (unspecified), Statin (unspecified)
184015 is seq 01 of 185524 seq02.

Report Detail

Case Number: 184184 **Seq:** 1 **Gender:** F
Reported: 19/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 63Y
Onset Date: 20/03/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia	Fluids restricted. Treated for respiratory infection/failure and UTI

Medicine Details:

CELEBREX (Other drug) **Reason:** Other rheumatoid arthritis
Capsule 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** Contin

PREDNISONE (Other drug) **Reason:** Other rheumatoid arthritis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** Contin

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 20/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/03/2003	Sodium		30/03/2002	122	
19/03/2003	Sodium		22/03/2002	128	
19/03/2003	Sodium		25/03/2002	136	

Additional Information:

Admitted for increased drowsiness and confusion. Dx: respiratory failure type II and possible UTI.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184240 **Seq:** 1 **Gender:** F
Reported: 20/03/2003 **Weight:** 73.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 16/03/2003 **DOB:**
Outcome: Recovered 18/03/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Heart rate increased	Caused or prolonged inpatient hospitalisation	Shivers, uncontrollable shaking, elevated temperature, increased heart rate and blood pressure, diaphoresis and diarrhoea.	
Blood pressure increased	Caused or prolonged inpatient hospitalisation		
Body temperature increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 12/03/2003 **Stopped:** 16/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient ceased taking avanza 30mg once daily. After 5 day wash out period, patient commenced therapy with aropax 20mg once daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184240 **Seq:** 1 **Gender:** F
Reported: 20/03/2003 **Weight:** 73.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 16/03/2003 **DOB:**
Outcome: Recovered 18/03/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 12/03/2003 **Stopped:** 16/03/2003

Laboratory Investigations:

Additional Information:

Patient ceased taking avanza 30mg once daily. After 5 day wash out period, patient commenced therapy with aropax 20mg once daily.

Report Detail

Case Number: 184240 **Seq:** 1 **Gender:** F
Reported: 20/03/2003 **Weight:** 73.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 16/03/2003 **DOB:**
Outcome: Recovered 18/03/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 12/03/2003 **Stopped:** 16/03/2003

Laboratory Investigations:

Additional Information:

Patient ceased taking avanza 30mg once daily. After 5 day wash out period, patient commenced therapy with aropax 20mg once daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184272 **Seq:** 1 **Gender:** F
Reported: 24/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: 13/03/2003 **DOB:** 10/01/1981
Outcome: Recovered 19/03/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swelling face	Required Visit to Doctor	Facial swelling mainly eyelids and lips.	Stopped Aropax, and given oral Terfenadine.

Medicine Details:

ZYPREXA (Other drug) **Reason:**
Tablet 3.7 Milligram Daily Oral
Batch: **Started:** 26/02/2003 **Stopped:**

MARVELON (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 22/07/2002 **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 23/02/2003 **Stopped:** 17/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking oroxine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184567 **Seq:** 1 **Gender:** F
Reported: 01/04/2003 **Weight:** 95.00
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 07/11/1957
Outcome: Recovered 20/03/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia	Life	Acute thrombocytopenia.	

Medicine Details:

INTERFERON ALFA-2A (Suspected) **Reason:** Other diseases of liver
Injection 30.0 Million Internationa Weekly
Batch: **Started:** 20/11/2002 **Stopped:** 13/02/2003

RIBAVIRIN (Suspected) **Reason:** Other diseases of liver
1.2 Gram Daily
Batch: **Started:** 20/11/2002 **Stopped:** 13/03/2003

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Oral application Dose Unspecified Daily Oral
Batch: **Started:** 06/02/2003 **Stopped:** 13/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/04/2003	Platelets				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184604 **Seq:** 1 **Gender:** U
Reported: 03/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 74
Onset Date: 22/03/2003 **DOB:** 13/04/1928
Outcome: Recovered 24/03/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 22/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Atenolol, Coversyl Pulus, Flecanide, Amlodipine and Simvastatin.

Report Detail

Case Number: 184605 **Seq:** 1
Reported: 03/04/2003
Hospitalisation: Admitted to hospital
Onset Date: 28/03/2003
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 88
DOB: 12/06/1914
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Nausea Vomiting		Hyponatraemia, nausea and vomiting.	Fluid replacement. Coversyl Plus and Paroxetine ceased and started Coversyl.

Medicine Details:

COVERSYL PLUS (Suspected) **Reason:** Essential benign hypertension
Tablet Daily Oral
Batch: **Started:** **Stopped:** 28/03/2003

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 28/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Somac, Atenolol and Aspirin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184632 **Seq:** 1 **Gender:** M
Reported: 03/04/2003 **Weight:** 79.00
Hospitalisation: **Age:** 53
Onset Date: 31/03/2003 **DOB:** 11/11/1949
Outcome: Recovered 01/04/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Agitation, headache, dirrhoea.	Aropax ceased.
Diarrhoea	Required Visit to Doctor		
Headache	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Only took 3 doses of Aropax.
Patient also taking Aspiring, Brufen, Nexium, Rhinocort and Zocor.
Known allergies: Paroextine - headache & anxiety.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 184770 **Seq:** 1 **Gender:** F
Reported: 09/04/2003 **Weight:** 75.00
Hospitalisation: **Age:** 93
Onset Date: 20/03/2003 **DOB:** 15/10/1909
Outcome: Recovered 05/04/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension Hyponatraemia		Postural hypotension due to hyponatraemia after taking Aropax for depression.	Ceased Aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 06/03/2003 **Stopped:** 27/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185163 **Seq:** 1 **Gender:** F
Reported: 22/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 18
Onset Date: 02/04/2003 **DOB:** 21/12/1984
Outcome: Recovered 06/04/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria	Severe	Severe urticaria rash.	Aropax ceased.

Medicine Details:

TRIFEME 28 (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 25/03/2003 **Stopped:** 02/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185214 **Seq:** 1 **Gender:** F
Reported: 29/04/2003 **Weight:** 90.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Severe	Began reducing Paroxtine after 8 months of 20mg mane. Reduced to 10mg daily for 7 days, then 10 mg alternate days for 7 days, then ceased altogether. Symptoms started approximately day 3 of reducing schedule and have escalated since then.	
Dissociation	Severe	Dissassociation, nausea, loss of apetite, feel like am constantly on a rollercoaster	
Affect lability	Severe	Inablity to control emotions, cry uncontollably for minimal if any reason.	
Disturbance in attention	Severe	Loss of concentration, feelings of anger, short tempered, amotivated	
Insomnia	Severe	Severe insomnia, severe nightmares,	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185214 **Seq:** 1 **Gender:** F
Reported: 29/04/2003 **Weight:** 90.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia	Severe		
Anger	Severe		
Anorexia	Severe		
Apathy	Severe		
Nausea	Severe		
Nightmare	Severe		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185391 **Seq:** 1 **Gender:** F
Reported: 04/05/2003 **Weight:** 58.00
Hospitalisation: **Age:** 23
Onset Date: 29/06/2002 **DOB:** 03/12/1978
Outcome: Recovered without treatment **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Severe	Moments of schizophrenia followed by suicidal thoughts.	
Agitation	Severe	Pyschiatric agitation/restlessness/dis-belief	
Depersonalisation	Severe	Withdrawal from "normal" social routines and sense of involvement. Total loss of sense of self	
Restlessness	Severe		

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:** Depression
Batch: **Started:** 28/06/2002 **Stopped:** 15/08/2002

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Capsule Oral
Batch: **Started:** 28/03/2002 **Stopped:** 28/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185633 **Seq:** 1
Reported: 08/05/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 48
DOB: 13/09/1954
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Occasional shaking, nausea, dizzy, paraesthesia and uncoordinated.	
Dizziness		Occasional shaking, nausea, dizzy, paraesthesia and uncoordinated.	
Nausea		Occasional shaking, nausea, dizzy, paraesthesia and uncoordinated.	
Paraesthesia		Occasional shaking, nausea, dizzy, paraesthesia and uncoordinated.	
Tremor		Occasional shaking, nausea, dizzy, paraesthesia and uncoordinated.	

Medicine Details:

Oxetine (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 02/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Changed from Aropax brand to Oxetine brand 1-2 months ago. Was Ok with Aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185676 **Seq:** 1
Reported: 07/05/2003
Hospitalisation:
Onset Date: 15/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 120.00
Age: 53
DOB: 06/12/1949
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression	Required Visit to Doctor	Suicidal thoughts, depression,	
Drug withdrawal syndrome	Required Visit to Doctor	Suicidal thoughts, depression,	
Hallucination	Required Visit to Doctor	Suicidal thoughts, depression,	
Panic attack	Required Visit to Doctor	Suicidal thoughts, depression,	
Suicidal ideation	Required Visit to Doctor	Suicidal thoughts, depression,	Extreme gradual weaning of

Medicine Details:

SERETIDE ACCUHALER NOS (Other drug) **Reason:** Asthma
Inhalation 2.0 Dose Unspecified Daily Inhalation
Batch: **Started:** **Stopped:**

ATACAND (Other drug) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Zoton.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185715 **Seq:** 1
Reported: 09/05/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood pressure increased		Patient commenced Aropax the next day after discontinuing Moclobemide and experienced an elevation in blood pressure from 160/90 to 180/90.	

Medicine Details:

MOCLOBEMIDE (Interaction) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

AROPAX (Interaction) **Reason:**
Daily Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185811 **Seq:** 1 **Gender:** F
Reported: 12/05/2003 **Weight:** 64.00
Hospitalisation: **Age:** 23Y
Onset Date: 15/04/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Night sweats		Night sweats	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 21/08/2000 **Stopped:** 01/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Night sweats ceased immediately after stopping medication.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 185888 **Seq:** 1 **Gender:** F
Reported: 14/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Self injurious behaviour Emotional distress		Self-harming, distressed, unable to speak	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 186118 **Seq:** 1 **Gender:** F
Reported: 21/05/2003 **Weight:** 70.00
Hospitalisation: **Age:** 32
Onset Date: 15/05/2003 **DOB:** 20/04/1971
Outcome: Recovered 16/05/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Rash on the face (cheeks). Rash very red and itchy.	

Medicine Details:

TRIQUILAR ED (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** S TERM **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rash occured after taking one tablet.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 186220 **Seq:** 1 **Gender:** F
Reported: 26/05/2003 **Weight:** 50.00
Hospitalisation: **Age:** 34
Onset Date: 15/03/2003 **DOB:** 20/05/1968
Outcome: Recovered 30/04/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cold sweat	Required Visit to Doctor	Night sweats, cold clamy at night and creepy crawly feeling on skin in daytime.	
Formication	Required Visit to Doctor	Night sweats, cold clamy at night and creepy crawly feeling on skin in daytime.	
Night sweats	Required Visit to Doctor	Night sweats, cold clamy at night and creepy crawly feeling on skin in daytime.	Ceased Aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/02/2003 **Stopped:** 20/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 186316 **Seq:** 1 **Gender:** F
Reported: 29/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 18Y
Onset Date: 01/01/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Aggression	Ceased Aropax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 01/06/2000 **Stopped:** 14/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of thyroid toxicosis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 186679 **Seq:** 1 **Gender:** F
Reported: 06/06/2003 **Weight:** 66.00
Hospitalisation: **Age:** 50
Onset Date: 14/05/2003 **DOB:** 23/01/1953
Outcome: Recovered 17/05/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		Felt floaghty and not with it, could not sleep, nausea, vomiting, insomnia, depersonalisation.	
Insomnia		Felt floaghty and not with it, could not sleep, nausea, vomiting, insomnia, depersonalisation.	
Nausea		Felt floaghty and not with it, could not sleep, nausea, vomiting, insomnia, depersonalisation.	
Vomiting		Felt floaghty and not with it, could not sleep, nausea, vomiting, insomnia, depersonalisation.	

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

TRAMAL (Interaction) **Reason:** Pain
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 14/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous nausea to digesic and anaesthetics.
Patient also took Diabex, Amaryl, Atacand and Livial.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 186941 **Seq:** 1 **Gender:** F
Reported: 17/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 05/06/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Nausea, severe tremor, shakiness.	
Tremor	Required Visit to Doctor		

Medicine Details:

PANAMAX (Other drug) **Reason:**
6.0 Dose Unspecified Daily
Batch: **Started:** 29/07/2002 **Stopped:**

AVAPRO HCT 150/12.5 (Other drug) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** 07/02/2003 **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 05/06/2003 **Stopped:** 13/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 187006 **Seq:** 1
Reported: 18/06/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 40
DOB: 08/09/1962
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Patient has been experiencing thoughts of self-harm (chopping her ear off), increased restlessness, nightmares and insomnia. She also experiences swollen limbs and hands in the morning which subsides during the day.	
Nightmare		Patient has been experiencing thoughts of self-harm (chopping her ear off), increased restlessness, nightmares and insomnia. She also experiences swollen limbs and hands in the morning which subsides during the day.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 29/04/1999 **Stopped:** 31/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 187006 **Seq:** 1
Reported: 18/06/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 40
DOB: 08/09/1962
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema		Patient has been experiencing thoughts of self-harm (chopping her ear off), increased restlessness, nightmares and insomnia. She also experiences swollen limbs and hands in the morning which subsides during the day.	
Restlessness		Patient has been experiencing thoughts of self-harm (chopping her ear off), increased restlessness, nightmares and insomnia. She also experiences swollen limbs and hands in the morning which subsides during the day.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 29/04/1999 **Stopped:** 31/05/2003

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 187006 **Seq:** 1
Reported: 18/06/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 40
DOB: 08/09/1962
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Self-injurious ideation		Patient has been experiencing thoughts of self-harm (chopping her ear off), increased restlessness, nightmares and insomnia. She also experiences swollen limbs and hands in the morning which subsides during the day.	Dose tapered gradually.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 29/04/1999 **Stopped:** 31/05/2003

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 187556 **Seq:** 1
Reported: 23/06/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 48
DOB: 27/09/1954
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Mood alteration, confrontational, aggressive, decreased zest for life.	
Mood altered		Mood alteration, confrontational, aggressive, decreased zest for life.	

Medicine Details:

PAXTINE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 17/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Paxtine was started sometime in November 2002.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 187829 **Seq:** 1 **Gender:** F
Reported: 27/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 20Y
Onset Date: 01/06/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epistaxis	Required Visit to Doctor	Patient complained of nose bleeds (epistaxis), described as being profuse.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** 01/06/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking levten, Multivitamins.
Prior to this, she had not had any nose bleeds.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 187929 **Seq:** 1
Reported: 27/06/2003
Hospitalisation: Admitted to hospital
Onset Date: 16/06/2003
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 86
DOB: 24/07/1916
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatremia.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 19/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Tritace, Noten and Losec.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 187977 **Seq:** 1
Reported: 02/07/2003
Hospitalisation:
Onset Date: 15/03/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 23
DOB: 24/03/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperaesthesia		Hyperasthesia hand and feet-flexor	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 24/02/2003 **Stopped:** 30/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Probable serotonergic with 8%.

Report Detail

Case Number: 188104 **Seq:** 1 **Gender:** F
Reported: 01/07/2003 **Weight:** 88.00
Hospitalisation: **Age:** 30
Onset Date: 21/06/2003 **DOB:** 21/07/1972
Outcome: Recovered 26/06/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia	Required Visit to Doctor	Flu-like symptoms, weakness, lethargy, sweating and prolonged sleeping.	
Hyperhidrosis	Required Visit to Doctor	Flu-like symptoms, weakness, lethargy, sweating and prolonged sleeping.	
Influenza like illness	Required Visit to Doctor	Flu-like symptoms, weakness, lethargy, sweating and prolonged sleeping.	
Lethargy	Required Visit to Doctor	Flu-like symptoms, weakness, lethargy, sweating and prolonged sleeping.	
Somnolence	Required Visit to Doctor	Flu-like symptoms, weakness, lethargy, sweating and prolonged sleeping.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 20/06/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax was also given at 10mg on the 12/06/03 - 19/06/03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 188159 **Seq:** 1 **Gender:** F
Reported: 03/07/2003 **Weight:** 55.00
Hospitalisation: **Age:** 38Y
Onset Date: 15/05/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus Drug withdrawal syndrome		"Zapping" sensation in the head, tinnitus and whoozy feeling, even if withdrawal is very slow.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/05/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions have happened at least 4 times. Even at end of dosage interal, notices these symptoms.
Also had same "zapping" while taking Efexor. No problems withdrawing.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 188503 **Seq:** 1 **Gender:** M
Reported: 14/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 05/04/1965
Outcome: Recovered 02/07/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of libido	Required Visit to Doctor	Loss of libido	Changed to Avandza.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 13/05/2003 **Stopped:** 25/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 188595 **Seq:** 1 **Gender:** F
Reported: 14/07/2003 **Weight:** 65.00
Hospitalisation: **Age:** 35
Onset Date: 26/06/2003 **DOB:** 12/03/1968
Outcome: Recovered 04/07/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia Drug withdrawal syndrome		Menorrhagia on D10 of normal cycle (168 pads and tampons used over one week period), immediately on stopping Aropax. No previous instances of heavy PV bleeding.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 16/11/2002 **Stopped:** 26/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No past history of heavy PV bleeding. Unsual cycle (x yrs) regular, with scantly bleeding 3/21. Not on hormonal contraception.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 188602 **Seq:** 1 **Gender:** M
Reported: 17/07/2003 **Weight:** 84.00
Hospitalisation: **Age:** 16
Onset Date: 22/02/2003 **DOB:** 19/06/1986
Outcome: Recovered 22/02/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	One hour after dose, became agitated, angry, dry mouth and tongue, "tight" mouth, clenching of teeth, sweating +++, "bruising" feeling in chest	Drug ceased
Anger	Required Visit to Doctor		
Chest pain	Required Visit to Doctor		
Dry mouth	Required Visit to Doctor		
Dystonia	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 19/02/2003 **Stopped:** 22/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 188602 **Seq:** 1 **Gender:** M
Reported: 17/07/2003 **Weight:** 84.00
Hospitalisation: **Age:** 16
Onset Date: 22/02/2003 **DOB:** 19/06/1986
Outcome: Recovered 22/02/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 19/02/2003 **Stopped:** 22/02/2003

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 189249 **Seq:** 1 **Gender:** F
Reported: 07/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 07/06/2003 **DOB:** 27/12/1963
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Headache and "absences" described as "like switched off a moment"	
Petit mal epilepsy		Petit mal epilepsy	
Visual disturbance		Visual disturbance seeing monvemts as "stopping and starting" or seeing "a scratched DVD playing"	

Medicine Details:

PIZOTIFEN MALATE (Other drug) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 07/06/2003 **Stopped:** 12/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 03/2003. Aropax was first initiated on 10mg/daily. No previous exposure to Paroxetine HCL, the patient experienced similar adverse events/complications. Suspected drug is cert/rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 189256 **Seq:** 1 **Gender:** F
Reported: 06/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 60
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Muscle spasms and Increased depression.	
Muscle spasms		Muscle spasms and Increased depression.	
Self-injurious ideation		Muscle spasms, increased depression and thoughts of self harm.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aropax taken for 2 years started in 2001. Other drugs: Celebrex, Flixotide, Foradile and Mogadon.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 189533 **Seq:** 1 **Gender:** M
Reported: 14/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: 04/08/2003 **DOB:** 18/02/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure (Convulsions).	

Medicine Details:

AROPAX (Suspected) **Reason:**

Batch: **Started:** **Stopped:** Contin

CLOZARIL (Suspected) **Reason:**

Tablet 675.0 Milligram Daily Oral

Batch: **Started:** 21/04/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stopped taking Clozaril sometime in May 1998

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 189571 **Seq:** 1 **Gender:** M
Reported: 15/08/2003 **Weight:** 45.00
Hospitalisation: **Age:** 85
Onset Date: **DOB:** 17/08/1917
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Creatinine renal clearance decrea		Renal impairment.	

Medicine Details:

RANITIDINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 25/06/2003

ROCALTROL (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 25/06/2003

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 19/12/2002 **Stopped:** 25/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/08/2003	Creatinine	0.04 - 0.12	19/12/2002	0.09	
15/08/2003	Creatinine	0.04 - 0.12	23/06/2003	0.48	
15/08/2003	Creatinine	0.04 - 0.12	25/06/2003	0.50	
15/08/2003	Creatinine	0.04 - 0.12	07/07/2003	0.48	
15/08/2003	Creatinine	0.04 - 0.12	14/07/2003	0.40	
15/08/2003	Creatinine	0.04 - 0.12	04/08/2003	0.33	
15/08/2003	Creatinine	0.04 - 0.12	15/08/2003	0.33	

Additional Information:

A renal physcician considered the patient's clinical scenario as "very much consistent with drug-induced interstitial nephritis".

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 189571 **Seq:** 1 **Gender:** M
Reported: 15/08/2003 **Weight:** 45.00
Hospitalisation: **Age:** 85
Onset Date: **DOB:** 17/08/1917
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

RANITIDINE (Suspected)			**Reason:**	
Batch:	**Started:**		**Stopped:**	25/06/2003
ROCALTROL (Suspected)			**Reason:**	
Batch:	**Started:**		**Stopped:**	25/06/2003
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression
Tablet	20.0 Milligram	Daily		Oral
Batch:	**Started:**	19/12/2002	**Stopped:**	25/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/08/2003	Urea	3.5 - 7.5	19/12/2002	7.5	
15/08/2003	Urea	3.5 - 7.5	23/06/2003	27.8	
15/08/2003	Urea	3.5 - 7.5	25/06/2003	29.2	
15/08/2003	Urea	3.5 - 7.5	07/07/2003	31.1	
15/08/2003	Urea	3.5 - 7.5	14/07/2003	31.4	
15/08/2003	Urea	3.5 - 7.5	04/08/2003	28.8	
15/08/2003	Urea	3.5 - 7.5	15/08/2003	27.0	

Additional Information:

A renal physcician considered the patient's clinical scenario as "very much consistent with drug-induced interstitial nephritis".

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 189777 **Seq:** 1 **Gender:** M
Reported: 22/08/2003 **Weight:** 70.00
Hospitalisation: **Age:** 16
Onset Date: 15/02/2003 **DOB:** 02/01/1987
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression	Required Visit to Doctor	Depression, suicidal ideation.	
Suicidal ideation	Required Visit to Doctor		

Medicine Details:

CANNABIS PREPARATION (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 189810 **Seq:** 1
Reported: 25/08/2003
Hospitalisation: Admitted to hospital
Onset Date: 30/04/2003
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 78
DOB: 16/08/1924
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nephritis interstitial	Life	Renal failure Acute, Nephritis interstitial	
Renal failure acute	Life	Renal failure Acute, Nephritis interstitial	
Malaise	Life		

Medicine Details:

ATORVASTATIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:** contin

ASPIRIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:** contin

PERINDOPRIL (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 30/04/2003

OMEPRAZOLE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/08/2003	Renal biopsy =				

Additional Information:

Omeprazole for reflux discontinued in december 2002. Patient started taking paroxetine in February 2003. Lit report Geevansinga N et al. Proton Pump Inhibitors and Acute Interstitial Nephritis. Clinical Gastroenterology and Hepatology 2006;597-604

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 189810 **Seq:** 1
Reported: 25/08/2003
Hospitalisation: Admitted to hospital
Onset Date: 30/04/2003
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 78
DOB: 16/08/1924
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 15/04/2003

Laboratory Investigations:

Additional Information:

Omeprazole for reflux discontinued in december 2002. Patient started taking paroxetine in February 2003. Lit report Geevansinga N et al. Proton Pump Inhibitors and Acute Interstitial Nephritis. Clinical Gastroenterology and Hepatology 2006;597-604

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 189931 **Seq:** 1
Reported: 28/08/2003
Hospitalisation:
Onset Date: 23/08/2003
Outcome: Not yet recovered

Gender: M
Weight: 100.00
Age: 59
DOB: 27/11/1943
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia		Anorexia.	Aropax ceased.
Pyrexia		Fever	
Nausea		Nausea	
Tremor		Tremor.	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 21/08/2003 **Stopped:** 25/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Amaryl, Astrix, Diaformin, Lipitor, Monoplus.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 190081 **Seq:** 1 **Gender:** M
Reported: 01/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 27/08/2003 **DOB:** 11/09/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Sedation Tremor		Diarrhoea, tremors, "stoned" (drugged out	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 27/08/2003 **Stopped:** 27/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 190217 **Seq:** 1 **Gender:** F
Reported: 04/09/2003 **Weight:** 73.00
Hospitalisation: **Age:** 73
Onset Date: 02/08/2003 **DOB:** 22/09/1929
Outcome: Recovered 19/08/2003 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypothermia Inappropriate antidiuretic hormon	Caused or prolonged inpatient hospitalisation	Suspected Siadh. Hypothermia	Medication ceased and fluid restricted. Over last 2 weeks has improved.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 03/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/09/2003	Sodium		02/08/2003	122	
04/09/2003	Temperature				Hypothermia 31.8 degrees

Additional Information:

Presented a month prior to this admission with Sodium decreased and hypothermia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 190776 **Seq:** 1 **Gender:** F
Reported: 23/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 82
Onset Date: 27/04/2003 **DOB:** 13/01/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia - Serum sodium nadir	Cease Aropax

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram 2 times Oral
Batch: **Started:** **Stopped:**

TRITACE (Suspected) **Reason:**
10.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2003	Sodium				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 190927 **Seq:** 1
Reported: 26/09/2003
Hospitalisation: Admitted to hospital
Onset Date: 08/09/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 19
DOB: 10/02/1984
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Dyskinesia Dystonia Mydriasis		Akathisia, all limbs affected but mainly akathisia in legs, dyskinesia, dystonia, mydriasis.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 04/09/2003 **Stopped:** 08/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 190969 **Seq:** 1 **Gender:** F
Reported: 29/09/2003 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 27/08/2003 **DOB:** 18/09/1968
Outcome: Recovered 27/08/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Drowsy post surgery for longer than	Sevofluranes
Tremor		Localised migratory tremor after elective minor surgery.	
Mutism		Mutism	
Hypertonia		Patient hypertonic	
Serotonin syndrome		Serotonin syndrome	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

TRAMAL (Suspected) **Reason:** Pain
Injection 100.0 Milligram Daily Intravenous
Batch: **Started:** 27/08/2003 **Stopped:** 27/08/2003

TORADOL (Suspected) **Reason:** Pain
Injection 100.0 Milligram Daily Subcutaneous
Batch: **Started:** 27/08/2003 **Stopped:** 27/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 190969 **Seq:** 1
Reported: 29/09/2003
Hospitalisation: Admitted to hospital
Onset Date: 27/08/2003
Outcome: Recovered 27/08/2003

Gender: F
Weight: 60.00
Age: 34
DOB: 18/09/1968
Causality: Causality possible

Reaction Detail

Medicine Details:

PROPOFOL (Suspected)			**Reason:**		
Injection	150.0	Milligram	Daily		Intravenous
Batch:	**Started:**			**Stopped:**	
ATRACURIUM BESYLATE (Suspected)			**Reason:**		
Injection	15.0	Milligram	Daily		Intravenous
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 190990 **Seq:** 1 **Gender:** F
Reported: 29/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 77
Onset Date: 22/07/2003 **DOB:** 20/04/1926
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	Ankle oedema	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 18/03/2003 **Stopped:** 22/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 191118 **Seq:** 1
Reported: 07/10/2003
Hospitalisation:
Onset Date: 28/09/2003
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 99U
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Required Visit to Doctor	"Wierd" as if brain does not register vision, whenever move eyes in any direction even though see vision, "zapping" sensation behind eyes, tremors, nausea and vomiting, generalised headache.	
Abnormal sensation in eye	Required Visit to Doctor		
Headache	Required Visit to Doctor		
Nausea	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 28/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction was third episode of same, episodes relate to withdrawal symptoms to Aropax.
Patient previously took Aropax from December 2002 to July 2003.
Patient was born in January 1982 (teenager).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 191118 **Seq:** 1
Reported: 07/10/2003
Hospitalisation:
Onset Date: 28/09/2003
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 99U
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Required Visit to Doctor		
Visual disturbance	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 28/09/2003

Laboratory Investigations:

Additional Information:

Reaction was third episode of same, episodes relate to withdrawal symptoms to Aropax.
Patient previously took Aropax from December 2002 to July 2003.
Patient was born in January 1982 (teenager).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 191233 **Seq:** 1 **Gender:** F
Reported: 13/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: 15/09/2003 **DOB:** 26/02/1959
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

AMITRIPTYLINE HYDROCHLORIDE (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

CLOZARIL (Interaction) **Reason:**
Tablet 12.0 Milligram Daily Oral
Batch: **Started:** 31/05/1993 **Stopped:** contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/10/2003	Electroencephalog				
13/10/2003	Other data				

Additional Information:

History of three seisures over the last 30 years but was not receiving anti-epileptic treatment.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 191298 **Seq:** 1 **Gender:** M
Reported: 14/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Tachycardia		Patient developed psychosis and	

Medicine Details:

AROPAX (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Male patient, J.K. was prescribed Aropax for anxiety. Developed psychosis and tachycardia sometime in 1999 whilst taking Aropax. Patient would not give doctors details, nor any other details about this case.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 191407 **Seq:** 1 **Gender:** F
Reported: 20/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 40Y
Onset Date: 15/08/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Headache Nausea Vertigo		Drug withdrawal syndrome, Vertigo,	

Medicine Details:

LABETALOL HYDROCHLORIDE (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 27/07/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Oral Paroxetine was discontinued in August 2003 - dose tapered gradually.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 191808 **Seq:** 1 **Gender:** M
Reported: 03/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 23Y
Onset Date: 29/10/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	SEIZURES	Diazepam on admission to

Medicine Details:

ALCOHOL (Suspected) **Reason:**
Oral Liquid 18.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 24/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2003	Electroencephalog				
03/11/2003	Other data				
03/11/2003	Other data				
03/11/2003	Serum drug level				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192105 **Seq:** 1 **Gender:** F
Reported: 11/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rectal haemorrhage	Required Specialist Consultation	Rectal haemorrhage, abdominal pain upper, rectal discharge, dyspoea.	
Abdominal pain upper	Required Specialist Consultation		
Dyspnoea	Required Specialist Consultation		
Rectal discharge	Required Specialist Consultation		

Medicine Details:

AROPAX (Suspected) **Reason:** Obsessive compulsive neurosis
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/11/2003	Other data				

Additional Information:

Patient stopped Aropax but restarted it due to her serotonin levels, on the advice of her doctor. She continued to experience stomach pain and mucous from her bowel, so once again, stopped Aropax on approximately 2 December 2003. Suspected Drug Positive Rechallenge.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192308 **Seq:** 1
Reported: 18/11/2003
Hospitalisation: Admitted to hospital
Onset Date: 07/10/2003
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism	Caused or prolonged inpatient hospitalisation	Bruxism and chin hypoaesthesia.	
Hypoaesthesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 04/02/2003 **Stopped:** 08/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took Paroxetine 30mg from 08/10/2003

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192333 **Seq:** 1 **Gender:** M
Reported: 19/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 46Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention Diarrhoea		Patient was hospitalised because he did not pass urine for 24 hours. Diarrhoea persisted for three weeks.	Catheter and discharged.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 21/03/2003 **Stopped:** 08/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

It was noted that the symptoms of urinary retention resolved following cessation of Paroxetine. After discontinuation of Paroxetine the patient developed diarrhoea and blood tests and colonoscopy was carried out at the time of this report.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192436 **Seq:** 1 **Gender:** F
Reported: 24/11/2003 **Weight:** 65.00
Hospitalisation: **Age:** 40Y
Onset Date: 06/11/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion		Patient noticed an increase in spontaneous bruising (no trauma).	

Medicine Details:

AROPAX (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Has had trials of various SSRI'S. Each time noticed increased spontaneous bruising.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192448 **Seq:** 1 **Gender:** F
Reported: 24/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome neona	Caused or prolonged inpatient hospitalisation	Drug withdrawal syndrome neonatal, drug exposure during pregnancy.	Dextrose infusion, antibiotic
Agitation neonatal	Caused or prolonged inpatient hospitalisation	neonatal jitteriness	
Hypertonia neonatal	Caused or prolonged inpatient hospitalisation	significant hypertonia and opisthotonoic	Facial oxygen and intermittent positive pressure ventilation

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

OLANZAPINE (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2003	Other data				
24/11/2003	Other data				

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724
Nordeng H and Spigest O. Treatment with selective serotonin re-uptake inhibitors in the thrid trimester of pregnancy. Drug Safety 2005; 28(7):556-581

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192448 **Seq:** 1 **Gender:** F
Reported: 24/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		
Foetal distress syndrome	Caused or prolonged inpatient hospitalisation		
Hypoglycaemia neonatal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

OLANZAPINE (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724
Nordeng H and Spigest O. Treatment with selective serotonin re-uptake inhibitors in the thrid trimester of pregnancy. Drug Safety 2005; 28(7):556-581

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192448 **Seq:** 1 **Gender:** F
Reported: 24/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Opisthotonus	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		
Tremor neonatal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

OLANZAPINE (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724
Nordeng H and Spigest O. Treatment with selective serotonin re-uptake inhibitors in the thrid trimester of pregnancy. Drug Safety 2005; 28(7):556-581

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192869 **Seq:** 1 **Gender:** F
Reported: 05/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 13
Onset Date: 02/12/2003 **DOB:** 03/10/1990
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack	Treated in outpatient department only	presented 3 nights running with florid panic attacks; has been hyperventilating => "blackouts" at home	Given Salbutamol and
Hyperventilation	Treated in outpatient department only		
Loss of consciousness	Treated in outpatient department only		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 40.0 Milligram 1 time Oral

Batch: **Started:** 01/11/2003 **Stopped:** 04/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192974 **Seq:** 1 **Gender:** F
Reported: 08/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 30/06/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oropharyngeal swelling Asthenia Chest pain Dizziness Dysphagia Pain in extremity Somnolence Vision blurred		Oropharyngeal swelling, chest pain, asthenia, dizziness, vision blurred, pain in extremity, dysphagia, somnolence.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Oxazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192991 **Seq:** 1 **Gender:** F
Reported: 09/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 42Y
Onset Date: 26/11/2003 **DOB:**
Outcome: Recovered 12/12/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaw disorder	Treated in outpatient department only	Jaw weakness	
Paraesthesia	Treated in outpatient department only	Pin and needles, tremor, can not eat, jaw weakness, lethargy.	Ceased Aropax.
Lethargy	Treated in outpatient department only		
Pain in jaw	Treated in outpatient department only		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** 26/11/2003 **Stopped:** 30/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Taken to hospital thinking it is neck pain related to prior car accident. Patient continued with medication. Symptoms got worse. Patient ceased and 4 days later felt better.
Symptoms after 4 days on paroxetine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 192991 **Seq:** 1 **Gender:** F
Reported: 09/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 42Y
Onset Date: 26/11/2003 **DOB:**
Outcome: Recovered 12/12/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Treated in outpatient department only		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** 26/11/2003 **Stopped:** 30/11/2003

Laboratory Investigations:

Additional Information:

Taken to hospital thinking it is neck pain related to prior car accident. Patient continued with medication. Symptoms got worse. Patient ceased and 4 days later felt better.
Symptoms after 4 days on paroxetine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 193240 **Seq:** 1
Reported: 17/12/2003
Hospitalisation:
Onset Date: 10/12/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 53
DOB: 29/04/1950
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation Chills Diarrhoea Headache Hyperhidrosis Mental status changes Nausea Tearfulness		Disorientation, nausea, diarrhoea, headache, tearful, sweating, shivering and altered mental state.	

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation
Tablet 100.0 Milligram As necessary Oral
Batch: **Started:** 03/12/2003 **Stopped:** 10/12/2003

VENLAFAXINE HYDROCHLORIDE (Interaction) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** 09/12/2003 **Stopped:** 10/12/2003

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 09/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Cephalexin, prednisolone, Seretide, Salbutamol.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 193422 **Seq:** 1 **Gender:** F
Reported: 22/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 36
Onset Date: 18/11/2003 **DOB:** 31/07/1967
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Experienced the feeling of electric shocks in various parts of body.	
Feeling abnormal		Sensation of falling.	
Myoclonus			
Nightmare			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 03/11/2003 **Stopped:** 26/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Concurrent medications included Herbal products and Vitamins (not St John's Wort). Symptoms occurred approximately 15 days after starting Paroxetine HCL.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 193546 **Seq:** 1 **Gender:** F
Reported: 05/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations	Caused or prolonged inpatient hospitalisation	Patient experienced palpitation, hot flush, tingling and elevated blood pressure.	Aropax ceased.
Blood pressure increased	Caused or prolonged inpatient hospitalisation		
Hot flush	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 193546 **Seq:** 1 **Gender:** F
Reported: 05/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 193548 **Seq:** 1
Reported: 05/01/2004
Hospitalisation:
Onset Date: 12/08/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 50
DOB: 11/07/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Abnormal liver function tests.	

Medicine Details:

Ethanol (DO NOT USE, CODE ALCOHOL) (Other drug) **Reason:**

Daily

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/01/2004	ALT = SGPT	5 - 40	12/08/2003	57	
05/01/2004	AST = SGOT	5 - 40	12/08/2003	42	
05/01/2004	Biochemistry				
05/01/2004	GGT = SGGT =	8 - 65	12/08/2003	99	

Additional Information:

The patient was a smoker and consumed alcohol daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 193984 **Seq:** 1 **Gender:** M
Reported: 19/01/2004 **Weight:** 84.00
Hospitalisation: **Age:** 38
Onset Date: 30/11/2003 **DOB:** 26/07/1965
Outcome: Recovered 01/12/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Drug therapy changed Sleep disorder		Feeling anxious - All day, never happened previously with Aropax, Sleep disorder, Drug therapy changed.	

Medicine Details:

MONOPRIL (Other drug) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

GenRx Paroxetine (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 28/11/2003 **Stopped:** 30/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Condition resolved with switch to Aropax brand.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 193991 **Seq:** 1 **Gender:** F
Reported: 19/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 37Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Disturbance in attention Dizziness Nausea Vertigo		Drug withdrawal syndrome, Vertigo, Dizziness, Nausea, Felt vague.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 194170 **Seq:** 1 **Gender:** F
Reported: 30/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 22/05/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Leukopenia	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Over the last two years the patient was found to have decreased white blood cells (leukopenia). Leukopenia has improved. Other drug therapy: naproxen

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 194197 **Seq:** 1 **Gender:** F
Reported: 02/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Aspiration Convulsion	Caused or prolonged inpatient hospitalisation	Hyponatraemia, Convulsion, Aspiration.	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 194409 **Seq:** 1 **Gender:** F
Reported: 09/02/2004 **Weight:** 90.00
Hospitalisation: **Age:** 43
Onset Date: 15/11/2003 **DOB:** 27/12/1959
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis psoriasiform	Required Visit to Doctor	Psoriaform / eczematous rash on palms of hands, very cherry, cracking bleeding palms.	
Eczema	Required Visit to Doctor		
Pruritus	Required Visit to Doctor		
Skin disorder	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/11/2003 **Stopped:** 31/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge. Previous similar reaction on 19/06/01.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 194674 **Seq:** 1
Reported: 16/02/2004
Hospitalisation:
Onset Date: 09/01/2004
Outcome: Not yet recovered

Gender: F
Weight: 80.00
Age: 24
DOB: 21/10/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Increased agitation, confusion, thinking abnormal - unable to think straight, violent behaviour - putting fist through glass	
Aggression	Required Visit to Doctor		
Confusional state	Required Visit to Doctor		
Thinking abnormal	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily
Batch: **Started:** 24/12/2003 **Stopped:** 01/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Ventolin, Quar 100.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 194706 **Seq:** 1
Reported: 18/02/2004
Hospitalisation: Admitted to hospital
Onset Date: 01/02/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 20
DOB: 19/09/1983
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Abdominal pain Chromaturia Faeces pale Jaundice		LFT's abnormal, blood bilirubin increased, jaundice, abdominal pain, faeces pale and chromaturia. Blood glucose increased, malaise, blood cholesterol increased, blood triglycerides increased. Six week history of polydipsia, nausea, vomiting and polyuria before hospitalisation.	Stopped Aropax

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Oral

Batch: **Started:** 14/12/2003 **Stopped:** 07/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/02/2004	ALT = SGPT	<50	01/02/2004	2865 iu/L	
18/02/2004	Bilirubin	<22	06/02/2004	579 umol/L	
18/02/2004	SAP = ALP	40 - 120	06/02/2004	180 iu/L	

Additional Information:

On further investigation, it was found that the patient was taking 'recreational drugs', possibly amphetamines. This was considered to be more likely the cause of the events.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 194813 **Seq:** 1 **Gender:** F
Reported: 23/02/2004 **Weight:** 60.00
Hospitalisation: **Age:** 40
Onset Date: 13/12/2003 **DOB:** 24/01/1963
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swollen tongue		Swollen tongue	Ceased drug.

Medicine Details:

PEPCIDINE (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 04/12/2003 **Stopped:** 02/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Started with 10mg, increased to 20mg and 3 days after this tongue swelled.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 194973 **Seq:** 1 **Gender:** U
Reported: 27/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 15/12/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia.	Ceased Paroxetine.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Daily
Batch: **Started:** 09/11/2003 **Stopped:** 25/11/2003

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Daily
Batch: **Started:** 12/12/2003 **Stopped:** 15/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2004	Sodium		09/12/2003	140	
27/02/2004	Sodium		14/12/2003	126	

Additional Information:

Patient also administered: Aspirin, Thiamine, Omeprazole, Lasix, Pravastatin, Spironolactone.
Previous course Paroxetine 09/11/2003 - 25/11/2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 195085 **Seq:** 1 **Gender:** F
Reported: 03/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 36Y
Onset Date: 01/03/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Feeling abnormal	Severe	"Unable to get out of bed or to leave the	
Dizziness	Severe	Dizziness, faintness, feeling abnormal (shakey), sweaty, achey and anxious. "Unable to get out of bed or to leave the house"	Nil at present. States she is currently bed-bound.
Anxiety	Severe		
Drug withdrawal syndrome	Severe		
Hyperhidrosis	Severe		
Pain	Severe		

Medicine Details:

PAXTINE (Suspected) **Reason:**

Tablet 30.0 Milligram 1 time Oral

Batch: **Started:** 20/08/2003 **Stopped:** 28/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 195244 **Seq:** 1
Reported: 10/03/2004
Hospitalisation:
Onset Date: 20/02/2004
Outcome: Recovered with sequelae

Gender: F
Weight: 0.00
Age: 40
DOB: 11/10/1963
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Life	Grand mal convulsion, loss of consciousness, fatigue, disorientation, amnesia	Paroxetine was continued
Amnesia	Life		
Disorientation	Life		
Fatigue	Life		
Loss of consciousness	Life		

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/11/2003 S TERM **Stopped:** Contin

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Acute tonsillitis
300.0 Milligram Daily
Batch: **Started:** 20/02/2003 **Stopped:** 20/02/2003

DOTHIEPIN HYDROCHLORIDE (Other drug) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had previously had a seizure on a high dose of Prothiaden and had received Paroxetine HCL previously without any problems. History of seizures and no know history of allergies, movement disorders, head injury, cerebral palsy, neurological handicap or congenital abnormality, diabetes or renal failure.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 195505 **Seq:** 1 **Gender:** F
Reported: 16/03/2004 **Weight:** 69.00
Hospitalisation: **Age:** 65
Onset Date: 24/02/2004 **DOB:** 22/10/1938
Outcome: Recovered 07/03/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Patient started feeling very nauseous and energetic, sick all day, continuous crying, vomiting in evening, hot flushes, felt suicidal	Aropax ceased, switched to Zoloft
Crying	Required Visit to Doctor		
Hot flush	Required Visit to Doctor		
Suicidal ideation	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

EDRONAX (Suspected) **Reason:** Depression
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 17/02/2004 **Stopped:** 07/03/2004

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 29/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Premarin, Vioxx, Lasix, Slow-K, Tilade, Caltrate, Granocol and Panamax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 195829 **Seq:** 1 **Gender:** F
Reported: 22/03/2004 **Weight:** 57.00
Hospitalisation: **Age:** 19
Onset Date: 15/03/2004 **DOB:** 25/06/1984
Outcome: Recovered 18/03/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Bilateral nipple discharge of clear and then yellow fluid.	Nil.

Medicine Details:

MICROGYNON 30 ED (Suspected) **Reason:** Painful menstruation
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Alternate days
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 195983 **Seq:** 1 **Gender:** F
Reported: 26/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 02/03/2004 **DOB:** 10/07/1966
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme increased Eosinophilia		Patient experienced elevated liver	Paroxetine ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** 10/01/2004 **Stopped:** 10/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/03/2004	Biochemistry				

Additional Information:

Transaminase levels were twice its normal limit.

Report Detail

Case Number: 196044 **Seq:** 1 **Gender:** F
Reported: 29/03/2004 **Weight:**
Hospitalisation: **Age:** 99U
Onset Date: 14/02/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Full-term baby whose mother had taken paroxetine 40mg daily up to approx. 18 hours prior to labour. Three hours after birth, the baby had the following symptoms:- fever, sweating, jitteriness of	Glucose 10% for hypoglycaemia. IV gentamicin, benzylpenicillin, phenobarbitone and phenytoin
Tonic clonic movements		Symptoms persisted and 48 hours later seizure-like activity noted with tonic/clonic movement of arms and legs followed by back arching, lip-smacking and apnoea. Phenobarbitone and phenytoin given. No further seizures. Baby discharges home on day 7- seizure free and well.	
Tremor neonatal		Tremor, agitation, hypoglycaemia, apnoea and some arching of back, abdominal	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 40.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2004	Abdomen X-ray				abdominal X-ray normal
28/03/2004	Biochemistry				Blood glucose 2.2 on day 0; lumbar puncture- all normal
28/03/2004	Blood culture				blood cultures (negative)
28/03/2004	C-Reactive Protein				CRP 22 normal
28/03/2004	Chest X-ray				chest X-ray normal
28/03/2004	Electroencephalog				EEG normal
29/03/2004	Haematology				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 196044 **Seq:** 1 **Gender:** F
Reported: 29/03/2004 **Weight:**
Hospitalisation: **Age:** 99U
Onset Date: 14/02/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal distension			
Agitation neonatal			
Dyskinesia			
Hyperhidrosis			
Hypoglycaemia neonatal			
Infantile apnoeic attack			
Opisthotonus			
Tardive dyskinesia			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 40.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2004	Magnetic				MRI, cranial ultrasound, lumbar puncture- all normal
28/03/2004	White blood cells				WBC normal.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 196051 **Seq:** 1 **Gender:** M
Reported: 29/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 01/09/2003 **DOB:** 14/08/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Query neuroleptic malignant, febrile, muscle aches, rigors and night sweats.	Treatment with diazepam, discontinuation of reboxetine and amisulpride and unspecified dose reduction of paroxetine and periciazine.
Agitation	Caused or prolonged inpatient hospitalisation		
Chills			

Medicine Details:

Abilify (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

NEULACTIL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Batch: **Started:** 03/07/2003 **Stopped:**

EDRONAX (Suspected) **Reason:** Depression
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 26/08/2003 **Stopped:** 22/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aripiprazole later resumed as schizophrenic symptoms recurred.

Report Detail

Case Number: 196051 **Seq:** 1 **Gender:** M
Reported: 29/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 01/09/2003 **DOB:** 14/08/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Caused or prolonged inpatient hospitalisation		
Myalgia			
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		
Night sweats			

Medicine Details:

Abilify (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

NEULACTIL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Batch: **Started:** 03/07/2003 **Stopped:**

EDRONAX (Suspected) **Reason:** Depression
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 26/08/2003 **Stopped:** 22/01/2004

Laboratory Investigations:

Additional Information:
Aripiprazole later resumed as schizophrenic symptoms recurred.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 196051 **Seq:** 1 **Gender:** M
Reported: 29/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 01/09/2003 **DOB:** 14/08/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

NEULACTIL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Batch: **Started:** 03/07/2003 **Stopped:**

EDRONAX (Suspected) **Reason:** Depression
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 26/08/2003 **Stopped:** 22/01/2004

Laboratory Investigations:

Additional Information:
Aripiprazole later resumed as schizophrenic symptoms recurred.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 196441 **Seq:** 1 **Gender:** F
Reported: 13/04/2004 **Weight:** 60.00
Hospitalisation: **Age:** 18Y
Onset Date: 15/01/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Required Visit to Doctor	Insomnia, amnesia and hallucinations.	Aropax and Stilnox ceased. Being treated with counselling.
Amnesia	Required Visit to Doctor		
Hallucination	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 30/11/2003 12 months

STILNOX (Suspected) **Reason:** Specific disorders of sleep
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 30/11/2003 11 months

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was self-administering escalating doses of Stilnox.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 196620 **Seq:** 1 **Gender:** M
Reported: 19/04/2004 **Weight:** 92.00
Hospitalisation: **Age:** 46
Onset Date: 05/04/2004 **DOB:** 15/04/1957
Outcome: Recovered 08/04/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Trismus		Trismus.	Ceased Avopax

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 196686 **Seq:** 1 **Gender:** F
Reported: 21/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 32Y
Onset Date: 15/05/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempts.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** 01/02/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient who twice tried to kill herself and two young daughters by gassing them in the family car in June 2003 has blamed antidepressants prescribed to her.
News article by O'Leary and Dortch, "Murder bid blamed on pill use", The West Australian, 20 April 2004. History: Bipolar II disorder, dysthymic disorder, family stress, marital problem. A past history of alcohol abuse and marijuana use.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 196746 **Seq:** 1 **Gender:** F
Reported: 23/04/2004 **Weight:** 75.00
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 10/05/1952
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction	Required Visit to Doctor	Photsensitive rash, severe cramps	Losec and Aropax ceased, Seretide changed to Symbicort.
Muscle spasms	Required Visit to Doctor		

Medicine Details:

Seretide 250/25 MDI (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LOSEC (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Prednisolone, Ranitidine, reboxetine, Risedronate, Terbutaline.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 197436 **Seq:** 1 **Gender:** F
Reported: 18/05/2004 **Weight:** 64.00
Hospitalisation: **Age:** 38
Onset Date: 21/03/2004 **DOB:** 09/07/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Required Visit to Doctor	Patient experienced Grand mal seizure.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 06/03/2004 **Stopped:** 20/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started on 10mg Aropax on 6/3/04 for 3 days, then increased to 20mg - felt vague and decreased to 10mg, then increased again to 20mg 3 days prior to seizure. Also taking Zantac, Blackmore's BioAce Excell, Calcium with D supplement and Livatone.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 197601 **Seq:** 1 **Gender:** F
Reported: 26/05/2004 **Weight:** 75.00
Hospitalisation: **Age:** 34
Onset Date: **DOB:** 21/09/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack Drug therapy changed		Panic attacks previously controlled with [redacted]	Change tablets from Paxtine back to Aropax.

Medicine Details:

FEFOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FOLIC ACID (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PAXTINE (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Alternate days Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Telephone consultation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 197842 **Seq:** 1 **Gender:** M
Reported: 03/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 33Y
Onset Date: 15/03/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Inability to ejaculate.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 14/03/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 197957 **Seq:** 1 **Gender:** F
Reported: 08/06/2004 **Weight:** 58.00
Hospitalisation: **Age:** 56Y
Onset Date: 29/05/2004 **DOB:**
Outcome: Recovered 03/06/2001 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia.	Stopped Paroxatine.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 29/05/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/06/2004	Sodium		29/05/2004	120 mmol/L	
08/06/2004	Sodium		25/04/2004	132 mmol/L	

Additional Information:

Other drugs taken: Seretide 500/50, Spiriva, Ventalin/Atrovent and Diazepam.

Report Detail

Case Number: 198124 **Seq:** 1
Reported: 15/06/2004
Hospitalisation:
Onset Date: 05/06/2004
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 34
DOB: 09/03/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Visit to Doctor	Serotonin syndrome, tachycardia, dizzy, sweating and mild confusion.	
Confusional state	Required Visit to Doctor		
Dizziness	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Tachycardia	Required Visit to Doctor		

Medicine Details:

ARTHRO-AID (Other drug) **Reason:** Other diseases of joint
Capsule 750.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:** Ongoing

PANADEINE FORTE (Other drug) **Reason:** Pain
Tablet Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:** Ongoing

AROPAX (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 01/01/2003 **Stopped:** 08/06/2004

SEROQUEL (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 05/06/2003 **Stopped:** 08/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198339 **Seq:** 1 **Gender:** F
Reported: 21/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthma	Required Visit to Doctor	Asthma worsened.	Paxtine ceased.

Medicine Details:

PAXTINE (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Increased asthma persisted until Paroxetine ceased. Same pattern with Clomipramine as dose increased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198357 **Seq:** 1 **Gender:** F
Reported: 21/06/2004 **Weight:** 100.00
Hospitalisation: **Age:** 49Y
Onset Date: 01/12/1994 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight increase (40 kg gain since 1994)	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198579 **Seq:** 1 **Gender:** F
Reported: 29/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 25/05/1963
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Required Visit to Doctor	Manic episode - unable to sleep, flight of	
Insomnia	Required Visit to Doctor		
Speech disorder	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198639 **Seq:** 1 **Gender:** M
Reported: 01/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 04/05/1979
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Completed suicide		Mother reported her son had started on Aropax and Lithium at the age of 20 years. Took both products for 4 years. Son began seeing a new Psychiatrist 12 months ago who gradually reduced his dosage of Lithium from 4 tabs per day, to half a tab per day. Aropax dosage remained constant over this period. Psychiatrist had reduced dosage of Lithium because patient was complaining of weight gain and alopecia. Throughout this period of 4 years, son complained to mother that medication only "masked the feelings of depression, but it's ...	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Oral
Batch: **Started:** L TERM **Stopped:**

LITHIUM CARBONATE (Suspected) **Reason:** Depression
Tablet 1.0 Gram Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198639 **Seq:** 1 **Gender:** M
Reported: 01/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 04/05/1979
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia Depression Drug ineffective Weight increased		... still there", and that he was "depressed about the meaning of life". Son comitted suicide this year at age 24 years.	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Oral
Batch: **Started:** L TERM **Stopped:**

LITHIUM CARBONATE (Suspected) **Reason:** Depression
Tablet 1.0 Gram Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198680 **Seq:** 1 **Gender:** M
Reported: 02/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Unpremeditated suicide attempt 15 months	

Medicine Details:

XANAX (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ALCOHOL (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient woke up 2 days later at the intensive care unit. Someone had found him because there was a fire. Doctor increased dose form 2 to 3 tablets daily. Patient "happy to still be on Aropax."

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198681 **Seq:** 1
Reported: 02/07/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 45Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizziness like as if "spinning out"	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 20/05/2002 S TERM **Stopped:** 26/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/07/2004	Electroencephalog				Sleep Deprivation EEG on 7th february 2003 showed little EEG
02/07/2004	Electroencephalog				EEG scan on 13th January 2003 indicated changes. Patient diagnosed with left temporal lobe epilepsy

Additional Information:

Three separate courses of Aropax for this patient. Each use and withdrawal resulted in similar though not identical symptoms

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198681 **Seq:** 1
Reported: 02/07/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 45Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Somnolence, Seizure. Patient reported seizure occurring 12 days after completing 2nd course of Aropax. - Patient began Aropax (20 mg dose) in July 2000. Took course for 6 months, then came off Aropax. Patient recommenced Aropax on the 20th May 2002 (at the 20mg dose) and completed course on the 26th December 2002, dose was tapered down. Through both courses of Aropax, patient felt "very sleepy and doctor felt I had serotonin effect and that Aropax had caused ...	Epilim commenced 1st February 2003 continued until 10th March 2004

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** S TERM **Stopped:**

AROPAX (Suspected) **Reason:**

20.0 Milligram Daily Oral

Batch: **Started:** 20/05/2002 S TERM **Stopped:** 26/12/2002

Laboratory Investigations:

Additional Information:

Three separate courses of Aropax for this patient. Each use and withdrawal resulted in similar though not identical symptoms

Report Detail

Case Number: 198681 **Seq:** 1
Reported: 02/07/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 45Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
		... sleep somnolence". On the 7th January 2003 (12 days after completing Aropax), patient had a seizure whilst driving vehicle and had a car accident (no injuries incurred). Dr. stated "Seizure was Post-ictal". On 10th of March 2004 patient recommenced Aropax. From 1st day felt pressure in her left ear "like I was in a plane", and extreme daytime somnolence. She had 2 sleep studies conducted in Hospital and Dr. diagnosed ...	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 20/05/2002 S TERM **Stopped:** 26/12/2002

Laboratory Investigations:

Additional Information:

Three separate courses of Aropax for this patient. Each use and withdrawal resulted in similar though not identical symptoms

Report Detail

Case Number: 198681 **Seq:** 1
Reported: 02/07/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 45Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ear pain Convulsion Drug withdrawal syndrome		... "pathological daytime somnolence". Patient stopped Aropax abruptly on the 5th of January 2004 without tapering dose (patient ran out of scripts). She experienced discontinuation symptoms for 1 week with "dizziness, tremor and like I was spinning out". felt pressure in left ear "like being in a	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 20/05/2002 S TERM **Stopped:** 26/12/2002

Laboratory Investigations:

Additional Information:
Three separate courses of Aropax for this patient. Each use and withdrawal resulted in similar though not identical symptoms

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198681 **Seq:** 1
Reported: 02/07/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/12/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 45Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		
Temporal lobe epilepsy	Caused or prolonged inpatient hospitalisation		
Tremor			

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 20/05/2002 S TERM **Stopped:** 26/12/2002

Laboratory Investigations:

Additional Information:
Three separate courses of Aropax for this patient. Each use and withdrawal resulted in similar though not identical symptoms

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198682 **Seq:** 1
Reported: 02/07/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 21
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient reported three episodes of seizures	Ceased Aropax

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient did not have a history of epilepsy or seizures.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198690 **Seq:** 1
Reported: 05/07/2004
Hospitalisation: Admitted to hospital
Onset Date: 19/06/2004
Outcome: Not yet recovered

Gender: F
Weight:
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia	Caused or prolonged inpatient hospitalisation	Baby had symptomatic hypoglycaemia, intrauterine growth retardation, jaundice and hypothermia.	
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		
Foetal growth retardation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** S TERM **Stopped:** Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198690 **Seq:** 1
Reported: 05/07/2004
Hospitalisation: Admitted to hospital
Onset Date: 19/06/2004
Outcome: Not yet recovered

Gender: F
Weight:
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypothermia	Caused or prolonged inpatient hospitalisation		
Jaundice	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** S TERM **Stopped:** Continuing

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 198744 **Seq:** 1 **Gender:** M
Reported: 06/07/2004 **Weight:** 100.00
Hospitalisation: **Age:** 51
Onset Date: 25/04/2004 **DOB:** 05/10/1952
Outcome: Recovered 12/06/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams	Required Visit to Doctor	Patient experienced vivid dreams.	

Medicine Details:

COVERSYL (Other drug) **Reason:** Essential benign hypertension
Tablet Dose Unspecified Oral
Batch: **Started:** 01/01/2000 **Stopped:**

MOBIC (Suspected) **Reason:**
Dose Unspecified Oral
Batch: **Started:** 01/01/2004 **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction only happens at 20mg dose of Aropax. Patient is well at 10mg/daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 198824 **Seq:** 1
Reported: 09/07/2004
Hospitalisation:
Onset Date: 28/06/2004
Outcome: Not yet recovered

Gender: F
Weight: 66.00
Age: 46
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Throat tightness Dizziness Feeling hot and cold Formication Hallucination, visual Vomiting		Throat feels closed to food, constant vomiting, dizziness, hot and cold, feeling of something crawling on her and hallucinations - seeing dead husband.	Aropax ceased. Lexapro started but has since been stopped.

Medicine Details:

Lexapro (Other drug) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 28/06/2004 **Stopped:** 06/07/2004

AROPAX (Suspected) **Reason:** Depression
60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 28/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rechallenge proposed.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 199402 **Seq:** 1 **Gender:** F
Reported: 26/07/2004 **Weight:** 64.00
Hospitalisation: **Age:** 29
Onset Date: 03/02/2004 **DOB:** 05/11/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria	Required Visit to Doctor	Hives.	Gradual withdrawal of drug.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 15/12/2003 **Stopped:** 15/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 199443 **Seq:** 1 **Gender:** M
Reported: 28/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 15/03/2004 **DOB:** 26/09/1972
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Required Visit to Doctor	Repeated jerking of limbs while asleep.	Aropax ceased.

Medicine Details:

EPILIM (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** 15/03/2004 **Stopped:** 15/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

PH: Epilepsy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 199707 **Seq:** 1
Reported: 05/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 21
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain upper	Caused or prolonged inpatient hospitalisation	severe stomach cramps	

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral application Dose Unspecified Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 199881 **Seq:** 1 **Gender:** F
Reported: 11/08/2004 **Weight:** 52.00
Hospitalisation: **Age:** 43
Onset Date: 30/07/2004 **DOB:** 26/01/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Required Visit to Doctor	Patient experienced Aropax withdrawal syndrome, when trying to cease. High level of anxiety, agitation, feeling generally unwell and dysphoric	Patient demanded return to
Agitation	Required Visit to Doctor		
Anxiety	Required Visit to Doctor		
Dysphoria	Required Visit to Doctor		
Malaise	Required Visit to Doctor		

Medicine Details:

BUPRENORPHINE HYDROCHLORIDE (Other drug) **Reason:**
1.0 Dose Unspecified
Batch: **Started:** **Stopped:**

Lexapro (Other drug) **Reason:**
Tablet 10.0 Milligram Oral
Batch: **Started:** 02/07/2004 **Stopped:**

MORPHINE SULPHATE (Other drug) **Reason:**
Injection 50.0 Milligram Daily Intravenous
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 200478 **Seq:** 1
Reported: 01/09/2004
Hospitalisation:
Onset Date: 09/08/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 79
DOB: 21/04/1925
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Visit to Doctor	Patient experienced acute itchy papulosquamous erythemous to trunk and limbs + urticarial lesions c/w lupus skin.	Topical Steriods given.
Rash papular	Required Visit to Doctor		
Systemic lupus erythematosus	Required Visit to Doctor		
Systemic lupus erythematosus ra	Required Visit to Doctor		
Urticaria	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Batch: **Started:** **Stopped:**

LAMISIL (Suspected) **Reason:** Dermatomycosis nos

250.0 Milligram Daily

Batch: **Started:** 15/05/2004 **Stopped:** 19/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/09/2004	Other data				Bx - c/w lupus and ANA/ENA negative, ESR normal.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 200847 **Seq:** 1
Reported: 14/09/2004
Hospitalisation:
Onset Date: 29/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 38
DOB: 16/04/1966
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Nausea, dizzy and diarrhoea.	
Diarrhoea	Required Visit to Doctor		
Dizziness	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 30/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 200868 **Seq:** 1 **Gender:** M
Reported: 14/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 91Y
Onset Date: 10/09/2004 **DOB:**
Outcome: Recovered 11/09/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epilepsy	Severe	Acute epilepsy attack while in hospital	clonazepam prn and carbamazepine 200mg bd

Medicine Details:

ASASANTIN SR (Other drug) **Reason:** No reason given
Capsule 2.0 Unit 2 times Oral
Batch: **Started:** **Stopped:**

PLAVIX (Other drug) **Reason:** No reason given
Tablet 75.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:** 0

SOMAC (Other drug) **Reason:** No reason given
Tablet 20.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

CLEXANE (Other drug) **Reason:** No reason given
Injection 20.0 Milligram 1 time Subcutaneous
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 200868 **Seq:** 1 **Gender:** M
Reported: 14/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 91Y
Onset Date: 10/09/2004 **DOB:**
Outcome: Recovered 11/09/2004 **Causality:** Causality probable

Reaction Detail

Medicine Details:

NEULACTIL (Other drug)			**Reason:** Hallucinations	
Tablet	2.0	Milligram	1 time	Oral
Batch:	**Started:** 28/08/2004			**Stopped:**
ISOSORBIDE MONONITRATE (Other drug)			**Reason:** No reason given	
Tablet	60.0	Milligram	1 time	Oral
Batch:	**Started:**			**Stopped:**
QUINATE (Other drug)			**Reason:** No reason given	
Tablet	300.0	Milligram	1 time	Oral
Batch:	**Started:**			**Stopped:**
FERRO-GRADUMET (Other drug)			**Reason:** No reason given	
Tablet	325.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 200868 **Seq:** 1 **Gender:** M
Reported: 14/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 91Y
Onset Date: 10/09/2004 **DOB:**
Outcome: Recovered 11/09/2004 **Causality:** Causality probable

Reaction Detail

Medicine Details:

CARDIZEM (Other drug)			**Reason:**	No reason given
	30.0 Milligram	Daily		Oral
Batch:	**Started:**		**Stopped:**	
AROPAX (Suspected)			**Reason:**	Depression
	20.0 Milligram	1 time		Oral
Batch:	**Started:** 02/03/1994		**Stopped:**	10/09/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 201076 **Seq:** 1 **Gender:** M
Reported: 22/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 07/02/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sexual dysfunction		"sustained sexual performance"	
Amnesia		short term memory loss, "not remembering things"	
Suicidal ideation		suicidal thoughts on and off which he does not think are related to Aropax.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 201265 **Seq:** 1 **Gender:** F
Reported: 27/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 83Y
Onset Date: 20/07/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Hypokalaemia		Hyponatraemia, hypokalaemia.	Required medical attention, Rehydration with IV N Saline and Potassium30ml x 3, Chlorvescent IV

Medicine Details:

PANADOL (Other drug) **Reason:**
150.0 Milligram As necessary
Batch: **Started:** 17/04/2004 **Stopped:**

MOVICOL (Other drug) **Reason:**
Solution 2.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

ALEPAM (Other drug) **Reason:**
Tablet 15.0 Milligram Daily
Batch: **Started:** 21/04/2004 **Stopped:** 08/07/2004

SOLPRIN (Other drug) **Reason:**
Tablet 150.0 Milligram Daily
Batch: **Started:** 17/04/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/09/2004	Potassium		22/07/2004	4	
27/09/2004	Potassium		20/07/2004	2.5	
27/09/2004	Potassium		05/07/2004	3.8	
27/09/2004	Sodium		22/07/2004	137	
27/09/2004	Sodium		20/07/2004	116	
27/09/2004	Sodium		05/07/2004	139	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 201265 **Seq:** 1 **Gender:** F
Reported: 27/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 83Y
Onset Date: 20/07/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOCOR (Other drug)			**Reason:**	
Tablet	40.0	Milligram	Daily	
Batch:	**Started:**	17/04/2004	**Stopped:**	
NORMISON (Other drug)			**Reason:**	
	30.0	Milligram	Daily	
Batch:	**Started:**	06/05/2004	**Stopped:**	
STAPHYLEX (Other drug)			**Reason:**	
Capsule	1.0	Gram	Daily	
Batch:	**Started:**	13/07/2004	**Stopped:**	16/07/2004
DAPA-TABS (Suspected)			**Reason:**	
Tablet	2.0	Milligram	Daily	Oral
Batch:	**Started:**	23/06/2004	**Stopped:**	19/07/2004

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 201265 **Seq:** 1 **Gender:** F
Reported: 27/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 83Y
Onset Date: 20/07/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

COVERSYL (Suspected)			**Reason:**	Essential benign hypertension		
Tablet	8.0	Milligram	Daily		Oral	
Batch:	**Started:**	17/06/2004		**Stopped:**		
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression		
Tablet	20.0	Milligram	Daily		Oral	
Batch:	**Started:**	16/07/2004		**Stopped:**	18/07/2004	0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 201293 **Seq:** 1 **Gender:** M
Reported: 27/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 67
Onset Date: 05/07/2004 **DOB:** 21/05/1937
Outcome: Recovered 07/07/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Patient experienced confusion, hallucinations and serotonin syndrome.	
Hallucination	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMAL (Interaction) **Reason:** Pain
400.0 Milligram Daily
Batch: **Started:** 29/06/2004 **Stopped:**

Oxetine (Interaction) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/07/2004 **Stopped:** 06/07/2004

MS CONTIN (Other drug) **Reason:** Pain
500.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

VIOXX (Other drug) **Reason:** Pain
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 16/04/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient already in hospital.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 201293 **Seq:** 1 **Gender:** M
Reported: 27/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 67
Onset Date: 05/07/2004 **DOB:** 21/05/1937
Outcome: Recovered 07/07/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ENDEP (Other drug)			**Reason:**	Pain
Tablet	25.0	Milligram	Daily	Oral
Batch:	**Started:**	16/06/2004	**Stopped:**	
ARATAC (Other drug)			**Reason:**	Otr&nos disord of heart rhythm
Tablet	400.0	Milligram	Daily	Oral
Batch:	**Started:**	29/06/2004	**Stopped:**	

Laboratory Investigations:

Additional Information:
Patient already in hospital.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 201822 **Seq:** 1
Reported: 19/10/2004
Hospitalisation:
Onset Date: 30/09/2004
Outcome: Not yet recovered

Gender: F
Weight: 56.00
Age: 27
DOB: 04/07/1977
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neck pain	Required Visit to Doctor	Neck pain, abdominal pain, nausea, anorexia, malaise,Nocturial cold sweat,	Ceased Aropax
Abdominal pain	Required Visit to Doctor		
Anorexia	Required Visit to Doctor		
Cold sweat	Required Visit to Doctor		
Drug ineffective	Required Visit to Doctor		
Malaise	Required Visit to Doctor		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 0.0 Dose Unspecified Daily Oral
Batch: **Started:** 29/09/2004 **Stopped:** 13/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 201831 **Seq:** 1
Reported: 19/10/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 68
DOB: 14/02/1936
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation	tremor developed after approximately 1	Diazepam short term to control tremor. Has 4 drinks alcohol per night - asked to reduce

Medicine Details:

ALCOHOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 201967 **Seq:** 1 **Gender:** M
Reported: 22/10/2004 **Weight:** 70.00
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 13/01/1975
Outcome: Recovered 20/08/2004 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Required Visit to Doctor	The patient suffered chronic diarrhoea 8-10 times daily since commencing Aropax.	Aropax ceased

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 06/06/2001 L TERM **Stopped:** 20/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge. Patient stopped Aropax and bot better, started Aropax again and diarrhoea returned.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202202 **Seq:** 1
Reported: 01/11/2004
Hospitalisation:
Onset Date: 26/10/2004
Outcome: Not yet recovered

Gender: M
Weight: 60.00
Age: 24
DOB: 28/05/1980
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Patient developed a maculo papular rash on upper arms, face and back.	No treatment given.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 23/09/2004 **Stopped:** 27/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous recorded allergy to Amoxycillin causing swelling.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202339 **Seq:** 1 **Gender:** M
Reported: 05/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: 15/05/2004 **DOB:** 19/11/1974
Outcome: Recovered 15/06/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Over time the patient developed excessive aggression.	Aropax ceased - changed to Zoloft

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Alcohol use: yes - unknown quantity
Tobacco use: 15-25 per day.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202426 **Seq:** 1 **Gender:** F
Reported: 09/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 77
Onset Date: 15/04/2004 **DOB:** 08/01/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, auditory Hallucination, visual Nightmare		Auditory hallucinations , visual hallucinations and vivid nightmares.	Dose of Aropax reduced.

Medicine Details:

ROFECOXIB (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ATENOLOL (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CLOPIDOGREL (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ATORVASTATIN (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Concurrent medical conditions included impaired liver function and possible dementia.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202426 **Seq:** 1
Reported: 09/11/2004
Hospitalisation:
Onset Date: 15/04/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 77
DOB: 08/01/1927
Causality: Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Other drug)			**Reason:**	
Batch:	**Started:**		**Stopped:**	
DILTIAZEM HYDROCHLORIDE (Other drug)			**Reason:**	
				Oral
Batch:	**Started:**		**Stopped:**	
AROPAX (Suspected)			**Reason:**	Depression
Tablet	40.0 Milligram	Daily		Oral
Batch:	**Started:**	15/03/2004	**Stopped:**	

Laboratory Investigations:

Additional Information:

Concurrent medical conditions included impaired liver function and possible dementia.

Report Detail

Case Number: 202572 **Seq:** 1
Reported: 15/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 01/11/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 43
DOB: 20/02/1961
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient presented with new onset seizures believed due to combination of hyponatraemia and UTI. Decreased conscious level	Required intubation/ICU admission for seizures Sodium increased slowly, UTI treated also
Depressed level of consciousnes	Caused or prolonged inpatient hospitalisation		
Urinary tract infection	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CRANBERRY (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

BACLOFEN (Other drug) **Reason:**
45.0 Milligram
Batch: **Started:** **Stopped:**

DITROPAN (Other drug) **Reason:**
15.0 Milligram Oral
Batch: **Started:** **Stopped:**

FOLIC ACID (Other drug) **Reason:**
5.0 Milligram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/11/2004	Sodium				

Additional Information:

Patient also taking Caltrate/Ostelin 2 doses daily. Background - MS with lower limb spasticity, bladder dysfunction and constipation, osteoporosis, asthma and coeliac disease.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202572 **Seq:** 1
Reported: 15/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 01/11/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 43
DOB: 20/02/1961
Causality: Causality possible

Reaction Detail

Medicine Details:

VALIUM (Other drug)		**Reason:**	
	6.0 Milligram		
Batch:	**Started:**		**Stopped:**
IMURAN (Other drug)		**Reason:**	
	100.0 Milligram		
Batch:	**Started:**		**Stopped:**
SERETIDE ACCUHALER NOS (Other drug)		**Reason:**	
Inhalation			Inhalation
Batch:	**Started:**		**Stopped:**
VENTOLIN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Patient also taking Caltrate/Ostelin 2 doses daily. Background - MS with lower limb spasticity, bladder dysfunction and constipation, osteoporosis, asthma and coeliac disease.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202572 **Seq:** 1
Reported: 15/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 01/11/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 43
DOB: 20/02/1961
Causality: Causality possible

Reaction Detail

Medicine Details:

FOSAMAX ONCE WEEKLY TABLETS (Other drug)			**Reason:**	Osteoporosis	
Tablet	70.0	Milligram	Weekly		Oral
Batch:	**Started:**			**Stopped:**	
LEVLEN ED (Other drug)			**Reason:**	Contraception	
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PAXTINE (Suspected)			**Reason:**		
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	02/11/2004

Laboratory Investigations:

Additional Information:

Patient also taking Caltrate/Ostelin 2 doses daily. Background - MS with lower limb spasticity, bladder dysfunction and constipation, osteoporosis, asthma and coeliac disease.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202695 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 13/02/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

AROPAX (Suspected) **Reason:**

Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202700 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Agitation Suicide attempt		Suicidal ideation, many suicide attempts and agitation.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202714 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 21/07/1997 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury		Deliberate self harm.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202715 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 28/08/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Suicidal ideation		Suicidal ideation and suicide attempt.	

Medicine Details:

AROPAX (Suspected) **Reason:**
40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 202717 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

RISPERIDONE (Suspected) **Reason:**
3.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202743 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 17
Onset Date: **DOB:** 20/08/1987
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury		Multiple presentation of self harm.	

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202773 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 65
Onset Date: **DOB:** 23/06/1939
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient had mild hypomania and a death	

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202827 **Seq:** 1 **Gender:** F
Reported: 19/11/2004 **Weight:** 60.00
Hospitalisation: **Age:** 75
Onset Date: 14/04/2004 **DOB:** 16/07/1928
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Required Visit to Doctor	Patient developed headaches, stress "feeling not good and uptight in the mornings" and depression	Aropax ceased. Advised to try Zoloft
Depression	Required Visit to Doctor		
Stress	Required Visit to Doctor		

Medicine Details:

AMIZIDE (Other drug) **Reason:**
Tablet 50.0 Milligram Oral
Batch: **Started:** **Stopped:**

WARFARIN SODIUM (Other drug) **Reason:**
Tablet 5.0 Milligram Oral
Batch: **Started:** **Stopped:**

ASTRIX 100 (Other drug) **Reason:**
Capsule 100.0 Milligram Oral
Batch: **Started:** **Stopped:**

CALTRATE (Other drug) **Reason:**
Tablet 2.0 Gram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft 50mg/1 daily started on 04/05/04. Patient was adviced to take Aropax 20mg - 0.5 tab on 26/03/04, but dis not start on it till 07/04/04. Patient then stopped Aropax on 10/04/04, resumed again on 20/04/04, and stopped it only a few days after. at the time of her death she was not on Aropax.

Report Detail

Case Number: 202827 **Seq:** 1 **Gender:** F
Reported: 19/11/2004 **Weight:** 60.00
Hospitalisation: **Age:** 75
Onset Date: 14/04/2004 **DOB:** 16/07/1928
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

LIPEX (Other drug)			**Reason:**			
Tablet	20.0	Milligram			Oral	
Batch:	**Started:**			**Stopped:**		
ANGININE (Other drug)			**Reason:**			
Tablet	1.0	Dose Unspecified			Oral	
Batch:	**Started:**			**Stopped:**		
MURELAX (Other drug)			**Reason:**			
Tablet	2.0	Milligram			Oral	
Batch:	**Started:**	08/03/2004		**Stopped:**		
AROPAX (Suspected)			**Reason:**	Anxiety neurosis		
Tablet	10.0	Milligram	Daily		Oral	
Batch:	**Started:**	07/04/2004		**Stopped:**	22/04/2004	0

Laboratory Investigations:

Additional Information:

Zoloft 50mg/1 daily started on 04/05/04. Patient was adviced to take Aropax 20mg - 0.5 tab on 26/03/04, but dis not start on it till 07/04/04. Patient then stopped Aropax on 10/04/04, resumed again on 20/04/04, and stopped it only a few days after. at the time of her death she was not on Aropax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202853 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

CANNABIS PREPARATION (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
Oral Liquid Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202856 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation Akathisia Overdose Suicidal ideation		Homicidal and suicidal ideation, akathisia and overdose.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking amphetamines.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202860 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 202895 **Seq:** 1
Reported: 21/11/2004
Hospitalisation:
Onset Date: 01/07/1996
Outcome: Not yet recovered

Gender: M
Weight: 58.00
Age: 33
DOB: 21/08/1962
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Severe	Gradual "self-sabotage" of my marriage, career, health, professional standing and a corresponding spiralling of anxiety. After one year on a disability pension I was hired by Scope (previously SSOV). I was virtually unable to learn, 6 months later I was sacked. This led to increased depression and my dose was doubled to 40mg. Things didn't catch up wit me until November 2002 when a repeat of the benzo' abuse and self-sabotage saw me stealing	Virtually none. The reduction of anxiety and self-sabotage behaviour came about following my own research and decision to reduce paroxetine. The Psychotropic Drug Advisory Committee informed me via a telephone representative that finding a health professional to vouch for the ill effects of paroxetine was near impossible due to apprehension that they may be professionally embarrased or admitting
Personality change	Severe		

Medicine Details:

NITRAZEPAM (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ALPRAZOLAM (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

TEMAZEPAM (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ATIVAN (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Octazepam and Methodone.

Report Detail

Case Number: 202895 **Seq:** 1
Reported: 21/11/2004
Hospitalisation:
Onset Date: 01/07/1996
Outcome: Not yet recovered

Gender: M
Weight: 58.00
Age: 33
DOB: 21/08/1962
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Severe		

Medicine Details:

CANNABIS PREPARATION (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:**
Daily
Batch: Unknown **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet Milligram Daily Oral
Batch: Unknown **Started:** 01/07/1996 **Stopped:** 21/11/2004

Laboratory Investigations:

Additional Information:
Other drugs taken: Octazepam and Methodone.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 203017 **Seq:** 1
Reported: 24/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 04/09/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 23
DOB: 25/08/1981
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation	The patient experienced mania. Her sleep and oral intake were decreased and her energy increased. She was spending, shoplifting and had a sexual encounter with a stranger.	Intron A ceased. Sodium Valproate 500mg PO BID and Diazepam 5mg PO QID started.
Depression	Caused or prolonged inpatient hospitalisation		
Hypomania	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SALBUTAMOL (Other drug) **Reason:**
Inhalation 8.0 Dose Unspecified Inhalation
Batch: **Started:** **Stopped:**

ETHINYLOESTRADIOL-LEVONORGESTROL (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** 15/07/2004 **Stopped:** 0

INTRON A INJECTION (Suspected) **Reason:** Malignant melanoma of skin nos
Injection 30.0 Million Internationa Weekly
Batch: **Started:** 12/07/2004 **Stopped:** 22/06/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 203186 **Seq:** 1
Reported: 01/12/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/01/2004
Outcome: Unknown

Gender: M
Weight: 82.00
Age: 60
DOB: 05/03/1943
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Life	The patient developed bad trembling, high anxiety, chills, impaired vision, sweating, depression, bad dreams, headaches, low libido and hallucinations	Hospitalisation for 3 days.
Anxiety	Life		
Chills	Life		
Depression	Life		
Hallucination	Life		
Headache	Life		
Hyperhidrosis	Life		
Loss of libido	Life		
Nightmare	Life		

Medicine Details:

AROPAX (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

LOVAN (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Lexapro (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

DOTHEP (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 203186 **Seq:** 1
Reported: 01/12/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/01/2004
Outcome: Unknown

Gender: M
Weight: 82.00
Age: 60
DOB: 05/03/1943
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance	Life		

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Suspected)			**Reason:** Headache		
Tablet	80.0	Milligram	Daily		Oral
Batch:	**Started:** 15/10/2003			**Stopped:**	
ZOLOFT (Suspected)			**Reason:**		
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
EFEXOR-XR (Suspected)			**Reason:**		
Capsule	225.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 203423 **Seq:** 1 **Gender:** F
Reported: 13/12/2004 **Weight:** 68.00
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 12/12/1952
Outcome: Recovered 15/09/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthma		Patient started taking Aropax in 2001, within the next few months was diagnosed [illegible]	Has stopped all medications.

Medicine Details:

TRAMAL (Suspected) **Reason:** Vertebrogenic pain syndrome
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Suspected) **Reason:** Vertebrogenic pain syndrome
Tablet Oral
Batch: **Started:** **Stopped:**

ENDONE (Suspected) **Reason:** Vertebrogenic pain syndrome
Tablet Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 203423 **Seq:** 1 **Gender:** F
Reported: 13/12/2004 **Weight:** 68.00
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 12/12/1952
Outcome: Recovered 15/09/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

LOSEC (Suspected) **Reason:** Other diseases of esophagus
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 203598 **Seq:** 1 **Gender:** F
Reported: 15/12/2004 **Weight:** 0.00
Hospitalisation: **Age:** 57
Onset Date: **DOB:** 17/11/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Patient Report: Patient reporting adverse event she experienced whilst taking Aropax - eyesight affected. Patient started Aropax 4mths ago, initially on dose of 1 tab per day, which was increased to 2 tabs per day. She has recently noticed her "eyesight has deteriorated a little bit, and I'm using my glassses on a more regular basis". Her Optometrist feels that Aropax might be causing. Prior to this course, she took Aropax 2yrs ago for a period of 3-4mths. During this time she "noticed slight constipation, and bruising" and thought she needed to use her prescription glasses more regularly.	

Medicine Details:

AROPAX (Suspected) **Reason:**

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Concomitant medication: HRT, Multivitamin

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 203690 **Seq:** 1
Reported: 21/12/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 73
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage	Caused or prolonged inpatient hospitalisation	Patient experienced gastrointestinal	Admitted to ICU.

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 203967 **Seq:** 1 **Gender:** M
Reported: 06/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 23/06/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Colitis Anal haemorrhage Diarrhoea haemorrhagic		The patient experienced anal bleeding, bloody diarrhoea and colitis.	

Medicine Details:

QUETIAPINE (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** 01/07/2004 **Stopped:**

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** 01/12/2004 **Stopped:** 11/12/2004

IRON ORAL NOS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 204323 **Seq:** 1
Reported: 18/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 24/01/2004
Outcome: Recovered

Gender: M
Weight: 70.00
Age: 16
DOB: 23/07/1987
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Dystonic reaction, oculogyric crisis and spasms of the leg, back and facial muscles	Benztropine 2mg IM then oral
Muscle spasms	Caused or prolonged inpatient hospitalisation		
Oculogyration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Oral
Batch: **Started:** **Stopped:**

SOLIAN (Suspected) **Reason:** Depression
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/01/2005	Electrocardiograph				ECG: QTC borderline 0.42, otherwise normal.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 204629 **Seq:** 1
Reported: 25/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 27/12/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 76
DOB: 03/12/1927
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia and delirium.	Fluid restricted. Extreme confusion resulted in admission to psychiatric unit for possible psychosis. Tritace, Aropax and Ditropan ceased.
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

QUININE SULPHATE (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** L TERM **Stopped:**

TENOXICAM (Other drug) **Reason:**
Tablet 500.0 Microgram As necessary Oral
Batch: **Started:** L TERM **Stopped:**

ASPIRIN (Other drug) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

TRITACE (Suspected) **Reason:** Essential benign hypertension
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/01/2005	Sodium				123mmol/L.

Additional Information:

Report Detail

Case Number: 204629 **Seq:** 1
Reported: 25/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 27/12/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 76
DOB: 03/12/1927
Causality: Causality possible

Reaction Detail

Medicine Details:

AROPAX (Suspected)			**Reason:**	Anxiety neurosis	
Tablet	10.0	Milligram	Daily		Oral
Batch:	**Started:**		S TERM	**Stopped:**	
DITROPAN (Suspected)			**Reason:**		
Tablet	5.0	Milligram	Daily		Oral
Batch:	**Started:**		S TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 204653 **Seq:** 1
Reported: 25/01/2005
Hospitalisation: Treated in Accident/Emergency Department
Onset Date: 06/01/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 30
DOB: 05/05/1974
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction Acne Blister Dermatitis exfoliative Oedema	Required Specialist Consultation	On day 10 developed a severe photosensitivity reaction starting on her arms and later spreading to her legs and neck. The reaction started as an itchy purple rash with "small pimples", then the skin "puffed up" and began to peel "like a blister". One leg in particular was "like a third degree burn". Patient presented at the Emergency Department when she began experiencing swelling of her neck	Prednisolone, promethazine

Medicine Details:

AROPAX (Suspected) **Reason:**
0.0 Dose Unspecified Daily
Batch: **Started:** 27/12/2004 **Stopped:** 06/01/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient commenced Aropax on 27/12/04 at 1/3 tablet daily for 3 days then 1/2 tablet thereafter

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 204653 **Seq:** 1
Reported: 25/01/2005
Hospitalisation: Treated in Accident/Emergency Department
Onset Date: 06/01/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 30
DOB: 05/05/1974
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Specialist Consultation		Calamine Lotion, Pinetarsol
Pyrexia	Required Specialist Consultation		Paracetamol
Rash papular			
Urticaria			

Medicine Details:

AROPAX (Suspected) **Reason:**

0.0 Dose Unspecified Daily

Batch: **Started:** 27/12/2004 **Stopped:** 06/01/2005 0

Laboratory Investigations:

Additional Information:

patient commenced Aropax on 27/12/04 at 1/3 tablet daily for 3 days then 1/2 tablet thereafter

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 204810 **Seq:** 1 **Gender:** F
Reported: 01/02/2005 **Weight:** 0.00
Hospitalisation: **Age:** 61
Onset Date: **DOB:** 14/05/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increas		Patient Repport: Patient contacted GSK to enquire whether Aropax can affect the levels of liver enzymes. The patient has been on Aropax for approximately 6 months now. She was initially taking 20mg and then was increased to 40mg for a couple of months. The patient was then backtitrated back to 20mg for the past 4 months, and tomorrow will decrease to 10mg (self-initiated). According to the patient, test results in December 2004 and January 2005 have shown slightly elevated levels of ALT and AST. Apparently the January 2005 results were "2-3 points lower". The patient is currently also taking Murelax 15mg- 1 tablet at night and [illegible]	

Medicine Details:

AROPAX (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

dose related

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 204810 **Seq:** 1 **Gender:** F
Reported: 01/02/2005 **Weight:** 0.00
Hospitalisation: **Age:** 61
Onset Date: **DOB:** 14/05/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aspartate aminotransferase incre			

Medicine Details:

AROPAX (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

dose related

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 205845 **Seq:** 1 **Gender:** M
Reported: 08/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 31/01/2005 **DOB:** 14/04/1961
Outcome: Recovered 24/02/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased	Life	Patient developed leucopenia and	Withdrew Abilify 30mg and Paroxetine. Monitored WBC.
Neutrophil count decreased	Life		

Medicine Details:

Abilify (Suspected) **Reason:** Unspecified schizophrenia
Tablet 30.0 Milligram Weekly Oral
Batch: **Started:** 07/09/2004 **Stopped:** 18/02/2005 0

GenRx Paroxetine (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 07/09/2004 **Stopped:** 10/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/03/2005	Neutrophils		31/01/2005	1.7	
08/03/2005	Neutrophils		15/02/2005	1.65	
08/03/2005	Neutrophils		24/02/2005	2.3	
08/03/2005	White blood cells		31/01/2005	3.3	
08/03/2005	White blood cells		15/02/2005	3.5	
08/03/2005	White blood cells		24/02/2005	4.6	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 205944 **Seq:** 1 **Gender:** F
Reported: 10/03/2005 **Weight:** 66.00
Hospitalisation: **Age:** 59
Onset Date: 19/02/2005 **DOB:** 20/12/1945
Outcome: Recovered 02/02/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Required Visit to Doctor	The patient experienced urinary retention.	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 15/02/2005 **Stopped:** 26/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 206867 **Seq:** 1 **Gender:** F
Reported: 11/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Life	Patient became suicidal (was cutting her skin) and experienced weight loss. The report states the patient was losing weight prior to Edronax commencement.	Edronax ceased.
Self injurious behaviour	Life		
Suicidal ideation	Life		
Weight decreased	Life		

Medicine Details:

EDRONAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Major depression diagnosed 2004

Report Detail

Case Number: 206983 **Seq:** 1 **Gender:** F
Reported: 13/04/2005 **Weight:** 44.00
Hospitalisation: **Age:** 24Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		The patient experienced electric shock sensations in the head, sometimes on the face and hands. It was worse with alcohol and excercise and it always happened for the first 10 minutes after waking. The patient had no symptoms when withdrawing from 40mg to 20mg - the symptoms started when the dosage was	

Medicine Details:

ALCOHOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 15/09/1999 **Stopped:** 15/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: "Zaps" worse in withdrawal improved when drug ceased but have remained for 3 years with varying intensity.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 207133 **Seq:** 1 **Gender:** F
Reported: 18/04/2005 **Weight:** 65.00
Hospitalisation: **Age:** 15Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Life	The patient experienced tonic clonic seizure, pulseless electrical activity, pupils dilated, pupils were unresponsive to light, overdose, her heart rate fell, cardiac arrest, systolic blood pressure fell, was confused, sinus tachycardia, anuric, oliguric, increased creatinine, decreased phosphate, mild rhabdomyolysis, and first	Treatment includes cardiopulmonary resuscitation (CPR), ICU admission, external cardiac pacing, Midazolam for seizure, Adrenaline and Clopamine infusion, Atropine, Calcium Gluconate Sodium Bicarbonate and invasive arterial monitoring.
Anuria	Life		
Atrioventricular block first degree	Life		
Blood creatinine increased	Life		
Cardiac arrest	Life		

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Suspected) **Reason:**

7.0 Gram 1 time Oral

Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 240.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2005	Creatine	<160			CPK 4726 U/L two days after admission to ICU
18/04/2005	Creatinine				Creatinine 0.23 mmol/l peak over the next two days.

Additional Information:

The patient had been previously admitted to the hospital following overdoses.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 207133 **Seq:** 1 **Gender:** F
Reported: 18/04/2005 **Weight:** 65.00
Hospitalisation: **Age:** 15Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Life		
Drug ineffective	Life		
Electromechanical dissociation	Life		
Intentional overdose	Life		
Mydriasis	Life		
Myocardial infarction	Life		
Pupillary reflex impaired	Life		
Rhabdomyolysis	Life		
Shock	Life		

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Suspected) **Reason:**

7.0 Gram 1 time Oral

Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 240.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/04/2005	Other data				At the scene Glasgow coma scale:15 At the scene Electrocardiogram (ECG): Sinus rhytm. During cardiac arrest ECG: Pulseless idioventricular rate of 24 beats/min. In the Intensive Care Unit Chest X-ray: Patchy bilateral interstitial and alveolar infiltrates. Unknown date Urine drug screen: Showed Verapamil, large amounts of Sertraline and a small amount of Paroxetine as well as the presence ...

Additional Information:

The patient had been previously admitted to the hospital following overdoses.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 207133 **Seq:** 1 **Gender:** F
Reported: 18/04/2005 **Weight:** 65.00
Hospitalisation: **Age:** 15Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Suspected)			**Reason:**	
	7.0	Gram	1 time	Oral
Batch:	**Started:**			**Stopped:**
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**	
Tablet	240.0	Milligram	1 time	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
					... of Cannabinoids. Two days after admiission to intensive care unit ECG: Returned to normal following a period of first degreee block.
18/04/2005	Troponin	<0.4 mcg/L			Troponin 2.3 MCG/L two days after admission to ICU.

Additional Information:

The patient had been previously admitted to the hospital following overdoses.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 207142 **Seq:** 1 **Gender:** U
Reported: 18/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Foetal disorder	Congenital anomaly / birth defect	13 ribs	
Cleft palate	Congenital anomaly / birth defect	Cleft palate.	
Pierre Robin syndrome	Congenital anomaly / birth defect	Pierre-Robin syndrome	
Pierre Robin syndrome	Congenital anomaly / birth defect	Robin anomaly	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 15/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother also took amoxil for 1 week during pregnancy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 207431 **Seq:** 1
Reported: 27/04/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 25/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 85Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Inappropriate antidiuretic hormon		Patient developed hyponatraemia and suspected SIADH.	Stopped Paroxetine.

Medicine Details:

SIMVASTATIN (Other drug)		**Reason:**	Othr&unspec metabolic diseases
Batch:	**Started:**		**Stopped:**
NICORANDIL (Other drug)		**Reason:**	Angina pectoris w/o hyperten
Batch:	**Started:**		**Stopped:**
OMEPRAZOLE (Other drug)		**Reason:**	Other diseases of esophagus
Batch:	**Started:**		**Stopped:**
ASPIRIN (Other drug)		**Reason:**	Chron isch heart dis no hyper
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/04/2005	Sodium		25/03/2005	126	
27/04/2005	Urine Sodium		29/03/2005	35	
27/04/2005	Urine osmolality		29/03/2005	352	

Additional Information:

Report Detail

Case Number: 207431 **Seq:** 1
Reported: 27/04/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 25/03/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 85Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other drug)			**Reason:**	Unspecified psychosis	
Batch:	**Started:**			**Stopped:**	
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:**	16/03/2005		**Stopped:**	30/03/2005 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 207668 **Seq:** 1
Reported: 06/05/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 57
DOB: 13/07/1947
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Throat irritation Dry throat		Patient experienced burning dry throat, waked him at 4am. Burning lasted half an hour, but can last all day.	Ceased Aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 04/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On 21/04/05, patient reports "over 50%" improvement in symptoms. I think he has psychological obsessive drinking of water and milk.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 207792 **Seq:** 1
Reported: 13/05/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 65.00
Age: 59
DOB: 22/03/1946
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion Constipation		The patient experienced severe bruising and shocking constipation since starting Aropax	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** 06/02/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208045 **Seq:** 1
Reported: 20/05/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 28/04/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 81
DOB: 04/03/1924
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction Erythema Skin exfoliation		The patient experienced a photosensitivity skin reaction to the face and neck only. She developed erythema and mild desquamation of the skin.	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 05/05/2005

RISPERIDONE (Suspected) **Reason:** Unspecified psychosis
500.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208184 **Seq:** 1
Reported: 26/05/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 08/05/2005
Outcome: Not yet recovered

Gender: F
Weight: 62.00
Age: 59
DOB: 12/05/1945
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensation of heaviness Contusion Dermatitis Malaise Myalgia Rash papular		Patient experienced heavy legs, myalgia, a few bruises, malaise, spotting slitting rash tunk, papular rash, also perioral dermatitis.	Increased K+, mineral water, suspended Aropax and Livial.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/05/2005 **Stopped:** 12/05/2005

LIVIAL (Suspected) **Reason:** Menopausal symptoms
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** 03/05/2005 **Stopped:** 10/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208237 **Seq:** 1
Reported: 27/05/2005
Hospitalisation: Admitted to hospital
Onset Date: 23/09/1998
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 35Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	The patient experienced restlessness and agitation. The following day he experienced akathisia.	
Akathisia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected) **Reason:** Unspecified schizophrenia
4.0 Milligram Daily Oral
Batch: **Started:** 03/09/1998 **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 22/09/1998 **Stopped:**

PROPRANOLOL HYDROCHLORIDE (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 23/09/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I: RODOS.

Report Detail

Case Number: 208428 **Seq:** 1 **Gender:** F
Reported: 02/06/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 50
Onset Date: 15/10/2001 **DOB:** 16/03/1951
Outcome: Recovered 15/06/2005 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Incapacity/disability	During treatment with Aropax the patient noticed 'weird sensations in the face and skin, like a numbing sensation. I gradually noticed this feeling all over my face into my eyes and occasionally in the knees'.Approximately 3 years after starting paroxetine, in october 2001, the patient developed paraesthesia of the left side of the face, arm and leg. On november 2001, the patient developed right paraesthesia of the face and on 8 november 2001, she developed bilateral facial paraesthesia. Tests carried out for possible TIA, all test negative. Paraesthesia recurred on 19 November 2001, Febraury 2002, June	Aropax ceased.

Medicine Details:

REMIFEMIN (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

PROGYNOVA (Other drug) **Reason:** Menopausal symptoms
Tablet Oral
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 0.5 Dose Unspecified Alternate days Oral
Batch: **Started:** **Stopped:** 15/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug positive rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208443 **Seq:** 1 **Gender:** M
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 25/03/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Homicidal ideation		The patient was taking Aropax irregularly with a lot of alcohol. He experienced homicidal ideation and suicidal ideation.	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
Oral Liquid Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208449 **Seq:** 1 **Gender:** F
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 27/07/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient, who had been taking Aropax for six years, ceased using it over a couple of weeks. She developed acute akathisia with obsessive disturbing suicidal ideation.	Aropax changed to Prozac to facilitate withdrawal.
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 208451 is the second sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208461 **Seq:** 1 **Gender:** F
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 57
Onset Date: **DOB:** 25/02/1948
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Panic attack		When Aropax was increased the patient developed anxiety and panic attacks. She became intensely suicidal.	Aropax dosage was reduced.

Medicine Details:

AROPAX (Suspected) **Reason:**
60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rection was dose related.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208466 **Seq:** 1 **Gender:** M
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 30/06/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient became restless, developed akathisia and was suicidal and homicidal. He experienced a suicide attempt - tried to drive into a tree. He was also agitated.	Failed to respond to ECT or tricycles. Given Olanzapine 10mg and Zuclopenthixol 300mg
Agitation	Caused or prolonged inpatient hospitalisation		
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208539 **Seq:** 1 **Gender:** F
Reported: 07/06/2005 **Weight:** 63.00
Hospitalisation: **Age:** 21Y
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	Completed suicide, overdose, drug toxicity.	
Drug toxicity	Death		
Overdose	Death		

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

CARBAMAZEPINE (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

THIORIDAZINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
Oral Liquid Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/06/2005	Other data				Toxicity results: Chest blood carbamazepine at 18mg/L, 28mg/kg in liver and 610mg in stomach; chest blood paroxetine at 2.7mg/L and 26mg/kg in liver; chest blood thioridazine at 3.7mg/L and 12mg/kg in liver with the metabolites mesoridazine not detected in blood or liver, and sulforidazine not detected in liver but detected in chest blood at 0.1mg/L. Lamotrigine chest blood concentration was 39mg/L (Table 1).

Additional Information:

The deceased had been on lamotrigine for over three years and was taking a dosage of 600mg/day at the time of death. Journal of Forensic Sciences - Postmortem Investigation of Lamotrigine Concentrations, Maria G. Pricone, Christopher V. King, Olaf H. Drummer, Ken Opeskin and Iain M. McIntyre. Case 8.

Report Detail

Case Number: 208539 **Seq:** 1
Reported: 07/06/2005
Hospitalisation:
Onset Date:
Outcome: Death, maybe drug

Gender: F
Weight: 63.00
Age: 21Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

LAMICTAL (Suspected)			**Reason:**	Other&unspecified epilepsy	
Tablet	600.0	Milligram	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**	0	

Laboratory Investigations:

Additional Information:

The deceased had been on lamotrigine for over three years and was taking a dosage of 600mg/day at the time of death. Journal of Forensic Sciences - Postmortem Investigation of Lamotrigine Concentrations, Maria G. Pricone, Christopher V. King, Olaf H. Drummer, Ken Opeskin and Iain M. McIntyre. Case 8.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208684 **Seq:** 1 **Gender:** F
Reported: 14/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 77
Onset Date: 15/05/2005 **DOB:** 29/06/1927
Outcome: Recovered 23/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient experienced hyponatraemia, falls and complaining dizzy for a couple of days.	Lasix and Paxtine ceased. Patient placed on 600ml/day fluid restriction for 4 days. This was then relaxed to 1,000ml/day for further 3 days.
Dizziness	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DAPSONE (Other drug)		**Reason:**	Otr ecz&der due otr&unsp cause
Batch:	**Started:**		**Stopped:**
PANAFCORT (Other drug)		**Reason:**	Otr ecz&der due otr&unsp cause
Batch:	**Started:**		**Stopped:**
ZOCOR (Other drug)		**Reason:**	Othr&unspec metabolic diseases
Batch:	**Started:**		**Stopped:**
ROCALTROL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/06/2005	Sodium	136-144.			Sodium 103.
14/06/2005	Urine Sodium		15/05/2005	11	

Additional Information:

Report Detail

Case Number: 208684 **Seq:** 1 **Gender:** F
Reported: 14/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 77
Onset Date: 15/05/2005 **DOB:** 29/06/1927
Outcome: Recovered 23/05/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

BETALOC (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
MICARDIS (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
CARDIZEM CD (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
SLOW-K (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 208684 **Seq:** 1 **Gender:** F
Reported: 14/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 77
Onset Date: 15/05/2005 **DOB:** 29/06/1927
Outcome: Recovered 23/05/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

SEREPAX (Other drug)			**Reason:**	
Batch:	**Started:**			**Stopped:**
LASIX (Suspected)			**Reason:**	
Tablet	20.0 Milligram		Daily	Oral
Batch:	**Started:**			**Stopped:** 15/05/2005
PAXTINE (Suspected)			**Reason:**	Anxiety neurosis
Tablet	20.0 Milligram		Daily	Oral
Batch:	**Started:** 01/05/2005			**Stopped:** 15/05/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 209085 **Seq:** 1
Reported: 24/06/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 28Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient experienced weight gain of 12kg, (65-77kg) whilst on Aropax but not with	Ceased Aropax. Patient now trying Prozac.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 15/12/2003 **Stopped:** 15/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient lost 3-5kg when Aropax ceased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 209534 **Seq:** 1 **Gender:** F
Reported: 06/07/2005 **Weight:** 90.00
Hospitalisation: Required a visit to the doctor **Age:** 41
Onset Date: 18/06/2005 **DOB:** 08/11/1963
Outcome: Recovered 21/06/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Pruritus		Patient developed rash on face, neck and back, very itchy.	Zyrtec and Eurax cream.

Medicine Details:

GenRx Paroxetine (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 06/06/2005 **Stopped:** 20/06/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 210021 **Seq:** 1 **Gender:** F
Reported: 21/07/2005 **Weight:** 52.00
Hospitalisation: Admitted to hospital **Age:** 16
Onset Date: 10/09/2004 **DOB:** 14/07/1988
Outcome: Recovered 13/09/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Condition aggravated	Caused or prolonged inpatient hospitalisation	Patient experienced pre-existing depression which worsened on Paroxetine and worsening sleep patterns. No suicidal ideation since starting Paroxetine but had attemped self harm prior to admission.	
Depression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 13/08/2004 **Stopped:** 11/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 210021 **Seq:** 1 **Gender:** F
Reported: 21/07/2005 **Weight:** 52.00
Hospitalisation: Admitted to hospital **Age:** 16
Onset Date: 10/09/2004 **DOB:** 14/07/1988
Outcome: Recovered 13/09/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Self injurious behaviour	Caused or prolonged inpatient hospitalisation		
Sleep disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 13/08/2004 **Stopped:** 11/09/2004

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 210460 **Seq:** 1
Reported: 05/08/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 65.00
Age: 51
DOB: 22/11/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema		Patient developed angioedema.	

Medicine Details:

MOBIC (Suspected) **Reason:** Otr&unsp vertebrogen pain synd

15.0 Milligram Daily Oral

Batch: **Started:** 24/06/2005 **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 20/05/2005 **Stopped:** 19/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 210698 **Seq:** 1 **Gender:** M
Reported: 15/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 12/07/2005 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug interaction Anxiety Hallucination Palpitations		Patient experienced hallucinations, heart palpitations and had an anxiety attack on 14/07/05	Capadex stopped. Changed to Tramal/Zydol 50mg, 2 tabs every 4 hours. Dose reduced to 50mg every 4 hours.

Medicine Details:

CAPADEX (Interaction) **Reason:**
Capsule Oral
Batch: **Started:** 12/07/2005 **Stopped:** 0

AROPAX (Interaction) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 210702 **Seq:** 1 **Gender:** F
Reported: 15/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 77Y
Onset Date: 15/10/2002 **DOB:**
Outcome: Recovered 04/04/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient experienced weight gain 9kg over 6	Aropax ceased.

Medicine Details:

VENTOLIN (Other drug) **Reason:** Asthma
Batch: **Started:** **Stopped:**

ATROVENT (Other drug) **Reason:** Asthma
Batch: **Started:** **Stopped:**

FLIXOTIDE (Other drug) **Reason:** Asthma
Batch: **Started:** **Stopped:**

CIPRAMIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 210702 **Seq:** 1 **Gender:** F
Reported: 15/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 77Y
Onset Date: 15/10/2002 **DOB:**
Outcome: Recovered 04/04/2005 **Causality:** Causality probable

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily Oral
Batch: **Started:** 15/10/2002 **Stopped:** 15/04/2003

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 210857 **Seq:** 1
Reported: 17/08/2005
Hospitalisation:
Onset Date: 02/02/2004
Outcome: Not yet recovered

Gender: M
Weight: 78.00
Age: 34
DOB: 03/10/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Incapacity/disability	Severe withdrawal symptoms from discontinuing Aropax 20mg/day - sweating, agitation, hostility, confusion, diarrhoea, 8kg weight loss in 2 weeks, loss of appetite, disorientation	Administer immediately 20mg/day dose of Aropax
Agitation	Incapacity/disability		
Anorexia	Incapacity/disability		
Confusional state	Incapacity/disability		
Diarrhoea	Incapacity/disability		

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: All **Started:** 14/07/2001 **Stopped:** 02/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 210857 **Seq:** 1
Reported: 17/08/2005
Hospitalisation:
Onset Date: 02/02/2004
Outcome: Not yet recovered

Gender: M
Weight: 78.00
Age: 34
DOB: 03/10/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation	Incapacity/disability		
Hostility	Incapacity/disability		
Weight decreased	Incapacity/disability		

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: All **Started:** 14/07/2001 **Stopped:** 02/02/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 211136 **Seq:** 1 **Gender:** F
Reported: 26/08/2005 **Weight:** 42.00
Hospitalisation: **Age:** 95
Onset Date: **DOB:** 01/07/1910
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient experienced hyponatreamia.	Ceased Paroxetine, increased salt tabs to 1200mg daily, fluid restriction of 1.5L/day.

Medicine Details:

RISEDRONATE SODIUM (Other drug) **Reason:** Other diseases of bone
Batch: **Started:** **Stopped:**

Glucosamine Nos (Other drug) **Reason:** Osteoarthritis
Batch: **Started:** **Stopped:**

TIOPRONIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Seretide 250/25 MDI (Other drug) **Reason:** Otr respiratory systm diseases
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/08/2005	Sodium		05/08/2005	113	

Additional Information:

Had low sodium on previous admissions.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 211136 **Seq:** 1
Reported: 26/08/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 42.00
Age: 95
DOB: 01/07/1910
Causality: Causality possible

Reaction Detail

Medicine Details:

OXAZEPAM (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
CALCIUM NOS (Other drug)		**Reason:**	Other diseases of bone
Batch:	**Started:**		**Stopped:**
PARACETAMOL (Other drug)		**Reason:**	Unspecified arthritis
Batch:	**Started:**		**Stopped:**
COLOXYL WITH SENNA (Other drug)		**Reason:**	Constipation
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:
Had low sodium on previous admissions.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 211136 **Seq:** 1
Reported: 26/08/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 42.00
Age: 95
DOB: 01/07/1910
Causality: Causality possible

Reaction Detail

Medicine Details:

MOVICOL (Other drug) **Reason:** Constipation

Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 05/08/2005

Laboratory Investigations:

Additional Information:

Had low sodium on previous admissions.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 212215 **Seq:** 1
Reported: 05/10/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 15/05/2005
Outcome: Recovered

Gender: M
Weight: 75.00
Age: 17
DOB: 03/09/1987
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Panic attack		The patient experienced panic attacks.	Paroxetine ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily Oral
Batch: **Started:** 15/05/2005 **Stopped:** 15/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 212282 **Seq:** 1
Reported: 06/10/2005
Hospitalisation: Admitted to hospital
Onset Date: 26/08/2005
Outcome: Recovered

Gender: F
Weight: 68.00
Age: 84
DOB: 22/05/1921
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient experienced severe hyponatreamia - Na 114.	

Medicine Details:

CALTRATE (Other drug)		**Reason:**	Unspec vitamin deficien states
Batch:	**Started:**		**Stopped:**
OVESTIN (Other drug)		**Reason:**	Menopausal symptoms
Batch:	**Started:**		**Stopped:**
WARFARIN SODIUM (Other drug)		**Reason:**	Otr&nos disord of heart rhythm
Batch:	**Started:**		**Stopped:**
SOTALOL HYDROCHLORIDE (Other drug)		**Reason:**	Otr&nos disord of heart rhythm
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergies to Penicillin, Erythromycin, Tetracycline and Roxithromycin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 212282 **Seq:** 1
Reported: 06/10/2005
Hospitalisation: Admitted to hospital
Onset Date: 26/08/2005
Outcome: Recovered

Gender: F
Weight: 68.00
Age: 84
DOB: 22/05/1921
Causality: Causality probable

Reaction Detail

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 26/08/2005 **Stopped:** 06/09/2005

Laboratory Investigations:

Additional Information:

Allergies to Penicillin, Erythromycin, Tetracycline and Roxithromycin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 212314 **Seq:** 1
Reported: 07/10/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 79.00
Age: 32
DOB: 24/07/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Abdominal pain upper Crying Hyperhidrosis Hypoaesthesia Irritability		Patient began decreasing dose since no longer effective and experienced numbness in face-anaesthetic feeling, aggressive, irritable, crying, mood-swings, sweating, over-heating with exhaustion after exercise, vivid nightmares and stomach cramps. Symptoms began on decreasing dose from 30 to 25mg.	Patient started discontinuation of Aropax 08/05.

Medicine Details:

COVERSYL (Other drug) **Reason:**

Tablet 4.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 212314 **Seq:** 1
Reported: 07/10/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 79.00
Age: 32
DOB: 24/07/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mood swings Nightmare Therapy regimen changed			

Medicine Details:

COVERSYL (Other drug) **Reason:**

Tablet	4.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Depression

Tablet	30.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 212447 **Seq:** 1
Reported: 12/10/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 52
DOB: 21/12/1952
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	The patient experienced abnormal thinking not long after starting Aropax and thought she might have had seizures during sleep.	Aropax ceased. Lamictal for seizures, Zyprexa for psychosis
Convulsion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 212743 **Seq:** 1
Reported: 21/10/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Coordination abnormal Dry mouth		Patient developed nausea, dry mouth and in-cordination.	

Medicine Details:

ELOCON (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

BACTRIM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

TEMAZE (Other drug) **Reason:** Otr ecz&der due otr&unsp cause
Batch: **Started:** **Stopped:**

NORVASC (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 212745 is the seconds sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 212743 **Seq:** 1
Reported: 21/10/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PAXTINE (Suspected) **Reason:** Depression

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 28/02/2005 **Stopped:**

Laboratory Investigations:

Additional Information:

Report 212745 is the seconds sequence to this report.

Report Detail

Case Number: 212816 **Seq:** 1
Reported: 25/10/2005
Hospitalisation:
Onset Date: 07/12/2003
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 67
DOB: 27/02/1936
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium Abnormal behaviour Agitation Body temperature increased Disorientation Dysphasia		The patient developed delirium, disorientation to place and time, word-finding difficulties, severe agitation, unusual behaviour and mildly increased temperature to 37C.	Cessation of drugs, Olanzapine 2.5mg daily for agitation and observation

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression

Tablet 1.0 Dose Unspecified Daily Oral

Batch: **Started:** 03/12/2003 **Stopped:** 07/12/2003 0

HYPERICUM-ST JOHN'S WORT (Interaction) **Reason:** Depression

20.0 Millilitre Daily Oral

Batch: **Started:** 03/12/2003 **Stopped:** 07/12/2003 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took St John's Wort and Paroxetine for 4/7 - took 2 x recommended dose of Paroxetine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 213137 **Seq:** 1 **Gender:** M
Reported: 07/11/2005 **Weight:** 97.00
Hospitalisation: Required a visit to the doctor **Age:** 46
Onset Date: 24/10/2005 **DOB:** 22/07/1959
Outcome: Recovered 28/10/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema Photosensitivity reaction Rash		The patient developed erythematous, microvascular rash on the anterior chest and inner arms and a photosensitivity reaction	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
20.0 Milligram Daily Oral
Batch: **Started:** 15/11/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 213369 **Seq:** 1 **Gender:** M
Reported: 14/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 9
Onset Date: **DOB:** 04/11/1996
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Feeding disorder neonatal Developmental delay Drug exposure during pregnancy Feeding disorder neonatal Hypotonia Learning disorder		Patient experienced Ehrlers Danlos syndrome, feeding difficulties, learning problems, developmental delay, hypotonia, "metabolic problems.	

Medicine Details:

THYROXINE SODIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Paitent diagnosed with Ehlers- Danlos Syndrome

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 213590 **Seq:** 1 **Gender:** F
Reported: 18/11/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 38
Onset Date: 10/03/2005 **DOB:** 11/12/1966
Outcome: Recovered 12/03/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Chest discomfort Feeling hot Insomnia Palpitations Tremor		The patient experienced agitation, was hot, had palpitations, insomnia, chest tightness and tremor for two days.	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily Oral
Batch: **Started:** 09/03/2005 **Stopped:** 12/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 213676 **Seq:** 1 **Gender:** F
Reported: 23/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 25/09/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Hallucination Suicide attempt		The patient made a serious suicide attempt and experienced hallucinations while taking Aropax.	Zyprexa.

Medicine Details:

AROPAX (Suspected) **Reason:** Unspecified schizophrenia
40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reporter has special interest in psychotropics.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 213741 **Seq:** 1 **Gender:** M
Reported: 23/11/2005 **Weight:** 70.00
Hospitalisation: **Age:** 72Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Suicide attempt.	Patient weaning himself off Aropax and Diazepam.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

DIAZEPAM (Suspected) **Reason:** Anxiety neurosis
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 214205 **Seq:** 1
Reported: 12/12/2005
Hospitalisation: Required a specialist consultation
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 48
DOB: 01/06/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Back pain		The patient experienced unexplained pain syndrome and back pain after a relatively minor back injury	

Medicine Details:

AROPAX (Suspected) **Reason:** Menopausal symptoms

20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 214516 **Seq:** 1
Reported: 03/01/2006
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 41
DOB: 09/08/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Life	The patient experienced chronic, life threatening serotonin syndrome, akathisia, auditory hallucinations and neurotoxic delirium	Zyprexa.
Akathisia	Life		
Delirium	Life		
Hallucination, auditory	Life		

Medicine Details:

PHENERGAN (Other drug)
Reason:
Batch: **Started:** **Stopped:**

AROPAX (Suspected)
Reason:
Oral
Batch: **Started:** **Stopped:**

TRAMAL (Suspected)
Reason:
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 214550 **Seq:** 1 **Gender:** F
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 25/09/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Hallucination Psychotic disorder Suicide attempt		The patient experienced akathisia, had suicidal impulses and made a few attempts at suicide whilst on Aropax. She had features of psychosis and hallucinations - playing with her rabbit and there was no rabbit in the room.	Zyprexa 20mg.

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214552 is the second sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 214552 **Seq:** 1 **Gender:** F
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 25/09/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Hallucination Personality disorder Psychotic disorder Restlessness Suicide attempt		The patient experiences some restlessness. She becomes agitated and suicidal. She thinks her parents in the next room are talking about her. She believes in magic and clairvoyance and thinks she has clairvoyance. She believes in telepathy and sixth sense. She experiences hallucinations and fulfils all the criteria for	

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 40.0 Milligram Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214550 is the first sequence to this report.
A half an hour after she takes the Zyprexa tablets she sees visions, sees something fly past and then goes away. She like the Zyprexa.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 214643 **Seq:** 1 **Gender:** M
Reported: 06/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Weight decreased		Since starting Aropax the patient has been violent and lost weight.	

Medicine Details:

AROPAX (Suspected) **Reason:**
20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also on other medications including antipileptics.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 214776 **Seq:** 1
Reported: 10/01/2006
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 54.00
Age: 40
DOB: 23/09/1965
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haemorrhage Contusion		Patient experienced easily bruising-noticed bruises on her hips, thigh and knee and states she has "three bruises"	Full blood count required.

Medicine Details:

AROPAX (Suspected) **Reason:**

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2006	International	1.0-1.2	14/12/2005	1.0	
10/01/2006	Platelets	150-400	12/12/2005	374	
10/01/2006	Prothrombin time	10-14	14/12/2005	13 Sec	

Additional Information:

Patient has hereditary Haemorrhagic Telangiectasia (HHT) .

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 214902 **Seq:** 1 **Gender:** F
Reported: 12/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 57
Onset Date: 13/10/2005 **DOB:** 30/11/1947
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Drug interaction Drug level increased Fall Vision blurred		The patient experienced a number of falls, had increasing pain and was unable to lift right leg - right avulsion fracture of greater trochanter. She described increasing blurred vision and an increasing number of falls. Phenytoin level had increased.	Phenytoin held, Paroxetine changed to Mirtazapine. Right greater trochanteric fracture managed conservatively.

Medicine Details:

PHENYTOIN SODIUM (Interaction) **Reason:** Convulsions
400.0 Milligram Daily
Batch: **Started:** 28/09/2004 **Stopped:**

PAROXETINE NOS (Interaction) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** 15/09/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2006	Serum drug level				Phenytoin level 3/8 @0000 18 previous dose at 2200 2/8. Level 52 on 20/09/05, 130 13/10/05, 124 @2005 20/10/05 previous dose at 2015 19/10/05.

Additional Information:

Toxicity probably related to increased dose and addition of Paroxetine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 214924 **Seq:** 1
Reported: 12/01/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia		Patient experienced akathisia, exacabation of known motor restlessness.	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has Parkinson's disease and akathisia at times.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 215310 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 24/12/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Violent ideation Hyperhidrosis		The patient experienced sweats and shakes, had violent thoughts and was very angry. She went through a patch of being suicidal. She was very agitated and had to keep moving.	Ceased Aropax.

Medicine Details:

MORPHINE SULPHATE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

TRAMAL (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 215330 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 27/01/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Akathisia Insomnia Panic disorder Serotonin syndrome Tachycardia		The patient developed anxiety and panic. She probably could not sleep. She had tachycardia, suspected serotonin syndrome and akathisia.	Benzodiazepine, Temazepam and Clonazepam.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
Oral
Batch: **Started:** 31/12/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 215332 is the second sequence to this report. She took St John?s wort herself, which was ceased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 215332 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 27/04/2000 **DOB:**
Outcome: Death, maybe drug 11/09/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Death	The patient became seriously depressed, complained of headaches and clenching jaw, was unable to sleep and started to self-harm. She began to have suicidal thoughts, was hyperventilating, agoraphobic, had five suicide attempts, was confused, tearful, phobic, aggressive, experienced akathisia and suspected serotonin syndrome. She experienced weird dreams, was impulsive, light headed, had numbness and tingling limbs and committed suicide by hanging on 11 September 2000 on the second attempt.	
Agoraphobia	Death		
Akathisia	Death		

Medicine Details:

AROPAX (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily Oral
Batch: **Started:** 21/03/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 215330 is the first sequence to this report.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 215332 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 27/04/2000 **DOB:**
Outcome: Death, maybe drug 11/09/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death		
Self injurious behaviour	Death		
Serotonin syndrome	Death		
Suicide attempt	Death		

Medicine Details:

AROPAX (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

PROZAC (Suspected) **Reason:** Anxiety neurosis
20.0 Milligram Daily Oral
Batch: **Started:** 21/03/2000 **Stopped:**

Laboratory Investigations:

Additional Information:

Report 215330 is the first sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 215340 **Seq:** 1 **Gender:** F
Reported: 29/01/2006 **Weight:** 75.00
Hospitalisation: **Age:** 59Y
Onset Date: 21/01/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Drug withdrawal headache Drug withdrawal syndrome Lethargy Myalgia Nausea Sleep disorder		Zaps in head, nausea, a few nightmares, lethargy, giddiness, headaches, muscle aches, waking 3 to 4 times a night.	Exercise, drinking plenty of water, eat when feeling nauseous, trying to get plenty of rest when possible, accepting that reaction will eventually pass.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 20.0 Milligram 1 time Oral

Batch: **Started:** 01/11/2003 **Stopped:** 19/01/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 215354 **Seq:** 1 **Gender:** M
Reported: 30/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 02/11/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Personality change	Caused or prolonged inpatient hospitalisation	The patient experienced a personality change, agitation, depression, attempted suicide, akathisia, he was unstable, 'manic', had jittery legs, could not concentrate, could not sleep, but slept on and off all day, had no desire for sex, felt uneasy, got cranky and was irritated easily.	Efexor stopped, then restarted. He was taking Lithium.
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

LARGACTIL (Suspected) **Reason:** Depression
Batch: **Started:** **Stopped:**

NEULACTIL (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 215354 **Seq:** 1 **Gender:** M
Reported: 30/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 02/11/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		
Libido decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

LARGACTIL (Suspected) **Reason:** Depression
Batch: **Started:** **Stopped:**

NEULACTIL (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 215354 **Seq:** 1 **Gender:** M
Reported: 30/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 02/11/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation		
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

LARGACTIL (Suspected) **Reason:** Depression
Batch: **Started:** **Stopped:**

NEULACTIL (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 216731 **Seq:** 1 **Gender:** M
Reported: 28/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 11/03/2006 **DOB:** 09/04/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Body temperature increased	Caused or prolonged inpatient hospitalisation	Patient had been found non-responsive, unconscious, sedated and with frothing at mouth, increased body temperature and an increased CK	
Blood creatine phosphokinase in	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 30/08/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/03/2006	Creatine		11/03/2006	63000	

Additional Information:

No muscle rigidity.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 216787 **Seq:** 1 **Gender:** M
Reported: 29/03/2006 **Weight:** 90.00
Hospitalisation: **Age:** 50
Onset Date: 12/03/2006 **DOB:** 09/04/1955
Outcome: Recovered 23/03/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life	Patient in hostel was observed to slump from chair- no obvious fitting but described as frorhing from the mouth. Lost consciousness for 5 mins. When he awoke- agitatated, aggressive. Intubated for airway protection and admitted to ICU. In ICU, elevated CK, acute renal failure,febrile. Neuroleptic malignany syndrome	Intubation, Fluids and mannitol to maintain urine output; dantrolene and bromocriptine
Aggression	Life		
Agitation	Life		
Pyrexia	Life		

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

CLOZAPINE (Suspected) **Reason:**
Tablet 600.0 Milligram 1 time Oral
Batch: **Started:** 31/03/2005 **Stopped:** 12/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2006	Creatine				CK on admission 606 IU/L and peaked at 63328 on the 13/03/2006. Gradually decreased to normal (< 200 IU/L)on 24/03/3006. U&Es, FBE all normal. Micro: blood, urine, sputum, CSF- no growth

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 217049 **Seq:** 1
Reported: 05/04/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: M
Weight: 90.00
Age: 69
DOB: 09/07/1936
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Condition aggravated		Patient experienced severe aggravation of prexisting mild periodic limb movement	Aropax stopped 2005.

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 217062 **Seq:** 1 **Gender:** M
Reported: 06/04/2006 **Weight:** 80.00
Hospitalisation: **Age:** 99u
Onset Date: 18/02/2006 **DOB:**
Outcome: Recovered 20/02/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Agitation Confusional state Hypomania		Signs and symptoms of suspected serotonin syndrome, as diagnosed by emergency room doctor. Patient quite agitated, confused and hypomanic.	Tramal ceased, replaced with Oxycontin.

Medicine Details:

ENDEP (Interaction) **Reason:** Pain
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PAXTINE (Interaction) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRAMAL SR (Interaction) **Reason:** Pain
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/02/2006 0

TRAMAL (Interaction) **Reason:** Pain
100.0 Milligram Daily
Batch: **Started:** **Stopped:** 28/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 217062 **Seq:** 1 **Gender:** M
Reported: 06/04/2006 **Weight:** 80.00
Hospitalisation: **Age:** 99u
Onset Date: 18/02/2006 **DOB:**
Outcome: Recovered 20/02/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

CELEBREX (Other drug)			**Reason:**	Pain	
Capsule	200.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	0
CLOFEN (Other drug)			**Reason:**	Pain	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 217129 **Seq:** 1 **Gender:** F
Reported: 07/04/2006 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 82
Onset Date: 10/03/2006 **DOB:** 08/11/1923
Outcome: Recovered 12/03/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Lethargy	Caused or prolonged inpatient hospitalisation	Lethargy, confusion, general weakness secondary to hyponatraemia following commencement of Paroxetine.	
Asthenia	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PLAVIX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

NEXIUM (Other drug) **Reason:** Other diseases of esophagus
Batch: **Started:** **Stopped:**

NOTEN (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

FOSAMAX ONCE WEEKLY TABLETS (Other drug) **Reason:** Other diseases of bone
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/04/2006	Sodium				Sodium: 117.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 217129 **Seq:** 1 **Gender:** F
Reported: 07/04/2006 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 82
Onset Date: 10/03/2006 **DOB:** 08/11/1923
Outcome: Recovered 12/03/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVAPRO HCT 300/12.5 (Suspected) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 11/03/2006

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 07/03/2006 **Stopped:** 07/03/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 217178 **Seq:** 1 **Gender:** M
Reported: 07/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 81
Onset Date: **DOB:** 05/01/1925
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased		elevated perhexiline levels after commencing paroxetine	

Medicine Details:

PERHEXILINE MALEATE (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Interaction) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/04/2006	Other data				perhexiline levels within normal range (150-600) since 2003. Aropax commenced after 31/5/05. Perhexiline levels at 31/3/06 =

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 217551 **Seq:** 1 **Gender:** U
Reported: 20/04/2006 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 40
Onset Date: 13/03/2006 **DOB:** 29/03/1965
Outcome: Recovered 15/03/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyponatraemia		Seizure and low sodium.	

Medicine Details:

PAXTINE (Suspected) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 05/12/2005 **Stopped:** 13/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/04/2006	Sodium				Na+ 110.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 217854 **Seq:** 1 **Gender:** F
Reported: 02/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 12/09/2005 **DOB:** 20/03/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia		Alopecia - complete loss of hair.	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: 2 episodes of partial alopecia in past.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 218423 **Seq:** 1 **Gender:** F
Reported: 17/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 89
Onset Date: 29/04/2006 **DOB:** 17/05/1916
Outcome: Recovered 08/05/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient presented with hyponatraemia and generalised weakness.	Hydrene, Paroxetine and Glibenclamide ceased. Treated with Urea. Also on fluid restriction
Asthenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

NITRO-DUR (Other drug) **Reason:**
Patch, dermal 10.0 Milligram Daily Transdermal
Batch: **Started:** L TERM **Stopped:**

HYDRENE 25/50 (Suspected) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 15/02/2006 **Stopped:** 29/04/2006 0

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 29/04/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/05/2006	Sodium		08/05/2006	135	Na - 118, then went down to 113. Improved to 120 then

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 218423 **Seq:** 1 **Gender:** F
Reported: 17/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 89
Onset Date: 29/04/2006 **DOB:** 17/05/1916
Outcome: Recovered 08/05/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

GLIBENCLAMIDE (Suspected)				**Reason:**	Diabetes mellitus	
Tablet	5.0	Milligram	Daily		Oral	
Batch:	**Started:**		L TERM	**Stopped:**	03/05/2006	0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 218752 **Seq:** 1 **Gender:** F
Reported: 29/05/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 53
Onset Date: 01/01/1996 **DOB:** 28/05/1942
Outcome: Recovered 22/05/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration Barrett's oesophagus		Multiple frequently recurrent mouth ulcers plus barrett's oesaghegus. Patient started Aropax 10 years ago - mouth ulcers started shortly after this	Aropax ceased.

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/05/2006	Other data				Endoscopy - hiatus hernia + H.pyloric + colonoscopy - MAD.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 218864 **Seq:** 1 **Gender:** M
Reported: 01/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Facial pain Insomnia Pain Suicidal ideation		The patient experienced serotonin-like symptoms, facial pain, "clonus" insomnia and suicidal thoughts due to pain.	Tretment with Paroxetine and Baclofen was discontinued abruptly

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

BACLOFEN (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 218936 **Seq:** 1 **Gender:** M
Reported: 05/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 78
Onset Date: 03/02/2006 **DOB:** 29/08/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Lethargy Malaise		Patient developed hyponatraemia. Symptoms include feeling unwell and lethargy.	

Medicine Details:

OXYBUTYNIN HYDROCHLORIDE (Other drug)			**Reason:**	
Tablet	5.0	Milligram		Oral
Batch:	**Started:**		**Stopped:**	
SIMVASTATIN (Other drug)			**Reason:**	
Tablet	20.0	Milligram		Oral
Batch:	**Started:**		**Stopped:**	
CLOPIDOGREL (Other drug)			**Reason:**	
Tablet	75.0	Milligram		Oral
Batch:	**Started:**		**Stopped:**	
IRBESARTAN-HYDROCHLOROTHIAZIDE (Suspected)			**Reason:**	
Tablet	1.0		Daily	Oral
Batch:	**Started:**		**Stopped:**	04/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/06/2006	Sodium		03/02/2006	125	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 218936 **Seq:** 1
Reported: 05/06/2006
Hospitalisation:
Onset Date: 03/02/2006
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 78
DOB: 29/08/1927
Causality: Causality possible

Reaction Detail

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet	10.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 04/02/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 218942 **Seq:** 1
Reported: 05/06/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 14/12/2005
Outcome: Not yet recovered

Gender: F
Weight: 54.00
Age: 59
DOB: 20/01/1946
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ulcerative keratitis		Multiple corneal ulceration.	

Medicine Details:

METHOBLASTIN (Other drug) **Reason:**
10.0 Milligram Weekly
Batch: **Started:** L TERM **Stopped:**

OROXINE (Other drug) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

AROPAX (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 01/12/2005 **Stopped:** 29/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 219163 **Seq:** 1 **Gender:** M
Reported: 15/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 51Y
Onset Date: 24/01/2006 **DOB:**
Outcome: Recovered 01/02/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient developed hyponatraemia, nausea, vomiting, lassitude, confusion.	Fluid restriction, salt capsule 2
Confusional state	Caused or prolonged inpatient hospitalisation		
Fatigue	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 24/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/06/2006	Other data				GCS - 14.
15/06/2006	Sodium				Na - 111. Recovered to 134 on 01/02/06.

Additional Information:

Similar presentation last year SSRI induced SIADH, ulcerative colitis. MVA with T3-4 paraplegic, depression.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 219163 **Seq:** 1 **Gender:** M
Reported: 15/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 51Y
Onset Date: 24/01/2006 **DOB:**
Outcome: Recovered 01/02/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 24/01/2006

Laboratory Investigations:

Additional Information:

Similar presentation last year SSRI induced SIADH, ulcerative colitis. MVA with T3-4 paraplegic, depression.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 219285 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 51.00
Hospitalisation: **Age:** 45Y
Onset Date: 07/06/2006 **DOB:**
Outcome: Recovered 09/06/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed Anorexia Dry mouth Feeling hot Hyperhidrosis Malaise		Patient was taking half Aropax at night for 6 days. On the night of 6/6/06 Dr recommended she take 1 x Aropax at night, within 4 to 5 hours she was feeling very hot, sweating, nauseous, sick, dry mouth. For the next 48 hours, it was hard for her to keep her eyes open, she had no appetite, constantly felt like vomiting.	Dr told her to drop back to half a tablet, patient has now ceased the Aropax for now.

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 06/06/2006 **Stopped:** 06/06/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 219285 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 51.00
Hospitalisation: **Age:** 45Y
Onset Date: 07/06/2006 **DOB:**
Outcome: Recovered 09/06/2006 **Causality:** Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nausea			

Medicine Details:

AROPAX (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 06/06/2006 **Stopped:** 06/06/2006 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 219422 **Seq:** 1 **Gender:** F
Reported: 22/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: 14/12/2005 **DOB:** 16/02/1989
Outcome: Recovered 15/12/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mood swings	Caused or prolonged inpatient hospitalisation	Patient experienced poor concentration, developed further mood swings, period of probable dissociation, restlessness, poor sleep and confused thinking, agitated with some paranoid thinking.	Ceased Paroxetine
Agitation	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 30/11/2005 **Stopped:** 14/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 219422 **Seq:** 1 **Gender:** F
Reported: 22/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: 14/12/2005 **DOB:** 16/02/1989
Outcome: Recovered 15/12/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dissociation	Caused or prolonged inpatient hospitalisation		
Disturbance in attention	Caused or prolonged inpatient hospitalisation		
Paranoia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 30/11/2005 **Stopped:** 14/12/2005

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 219422 **Seq:** 1 **Gender:** F
Reported: 22/06/2006 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: 14/12/2005 **DOB:** 16/02/1989
Outcome: Recovered 15/12/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Poor quality sleep	Caused or prolonged inpatient hospitalisation		
Restlessness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 30/11/2005 **Stopped:** 14/12/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 220220 **Seq:** 1 **Gender:** F
Reported: 20/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 83
Onset Date: 14/06/2006 **DOB:** 07/04/1923
Outcome: Recovered 19/06/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dementia Condition aggravated Drug interaction		The patient had subtle but obvious changes in behavioral and psychological symptoms of dementia (BPSD).	Paroxetine was stopped.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

REMINYL (Interaction) **Reason:** Presenile dementia
Capsule 8.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CALTRATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PRAVACHOL (Other drug) **Reason:** Othr&unspec metabolic diseases
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 220220 **Seq:** 1 **Gender:** F
Reported: 20/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 83
Onset Date: 14/06/2006 **DOB:** 07/04/1923
Outcome: Recovered 19/06/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

PEPCIDINE (Other drug)		**Reason:**	Other diseases of esophagus
Batch:	**Started:**	**Stopped:**	
WARFARIN SODIUM (Other drug)		**Reason:**	Otr&nos disord of heart rhythm
Batch:	**Started:**	**Stopped:**	0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 220702 **Seq:** 1 **Gender:** F
Reported: 09/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 44Y
Onset Date: 14/07/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination Dizziness Hyperhidrosis Nausea	Caused or prolonged inpatient hospitalisation	Patient started 20mg tablets haaf a tablet daily, within 2-3 hours she started to experience dizziness, sweating, and severe nausea, she also experienced hallucinations for 2-3 dyas.	

Medicine Details:

PAXTINE (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 14/06/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 221012 **Seq:** 1 **Gender:** F
Reported: 24/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain		Pt had retrosternal chest pain following	Pt pain resolved once med was ceased.

Medicine Details:

AROPAX (Suspected) **Reason:**

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 221296 **Seq:** 1
Reported: 01/09/2006
Hospitalisation:
Onset Date: 22/04/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 83
DOB: 22/05/1922
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	Delerium secondary to serotonin syndrome, also myoclonic jerking and fever	
Myoclonus	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FRUSEMIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CELECOXIB (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DIGOXIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 221296 **Seq:** 1
Reported: 01/09/2006
Hospitalisation:
Onset Date: 22/04/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 83
DOB: 22/05/1922
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANTOPRAZOLE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SPIRONOLACTONE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

RAMIPRIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Suspected) **Reason:**
Capsule 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 02/05/2006

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 221296 **Seq:** 1
Reported: 01/09/2006
Hospitalisation:
Onset Date: 22/04/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 83
DOB: 22/05/1922
Causality: Causality possible

Reaction Detail

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Suspected)			**Reason:**		
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	02/05/2006
PAROXETINE HYDROCHLORIDE (Suspected)			**Reason:**		
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	01/05/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 222019 **Seq:** 1 **Gender:** F
Reported: 27/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Lymphocytosis Monocytosis Neutrophilia		Lymphocytosis, neutrophilia, monocytosis.	

Medicine Details:

AROPAX (Suspected) **Reason:**

Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 222154 **Seq:** 1
Reported: 04/10/2006
Hospitalisation: Admitted to hospital
Onset Date: 25/07/2006
Outcome: Recovered

Gender: F
Weight: 35.00
Age: 84
DOB: 07/07/1922
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Chest pain and visual hallucinations.	Paroxetine ceased.
Hallucination, visual	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TIOTROPIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

RABEPRAZOLE SODIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FRUSEMIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 0.5 Dose Unspecified Daily Oral
Batch: **Started:** 22/07/2006 **Stopped:** 25/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous S/E's with Sertraline.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 222763 **Seq:** 1 **Gender:** F
Reported: 30/10/2006 **Weight:** 53.00
Hospitalisation: Required a visit to the doctor **Age:** 38
Onset Date: 21/09/2006 **DOB:** 07/06/1968
Outcome: Recovered 26/09/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Dissociation Suicidal ideation		Inability to function -(couldnt work, eat, feed herself) felt like head wasnt hers, worsening depression and feeling suicidal. Symptoms worsened with continuing tablets therefore, stopped. Felt better the next afternoon.	Stopped Aropax.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis
10.0 Milligram Daily
Batch: **Started:** 20/09/2006 **Stopped:** 26/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 223483 **Seq:** 1 **Gender:** M
Reported: 26/11/2006 **Weight:** 70.00
Hospitalisation: **Age:** 24
Onset Date: 23/11/2006 **DOB:** 15/04/1982
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Incapacity/disability	Dizziness, paraesthesia, feelings of depersonalisation. Extreme lethargy.	Started back on 5mg after slowly cutting down. Will try to cease again
Depersonalisation	Incapacity/disability		
Drug withdrawal syndrome	Incapacity/disability		
Lethargy	Incapacity/disability		
Paraesthesia	Incapacity/disability		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Capsule 10.0 Milligram 1 time Oral
Batch: **Started:** 10/10/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 224314 **Seq:** 1
Reported: 27/12/2006
Hospitalisation: Admitted to hospital
Onset Date: 04/04/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 23
DOB: 01/05/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tourette's disorder	Caused or prolonged inpatient hospitalisation	Tourette's Syndrome - after one week of paroxetine use she developed movement disorder in her right arm and also abnormal movements in the upper body and neck.	
Tic	Caused or prolonged inpatient hospitalisation	Tourette's syndrome	
Dyskinesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Oxetine (Suspected) **Reason:**
Tablet 20.0 Milligram Oral
Batch: **Started:** 28/03/2003 **Stopped:** 28/04/2003 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Still unrecovered after 6 months

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 224314 **Seq:** 1
Reported: 27/12/2006
Hospitalisation: Admitted to hospital
Onset Date: 04/04/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 23
DOB: 01/05/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Movement disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Oxetine (Suspected) **Reason:**
Tablet 20.0 Milligram Oral
Batch: **Started:** 28/03/2003 **Stopped:** 28/04/2003 0

Laboratory Investigations:

Additional Information:

Still unrecovered after 6 months

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 225082 **Seq:** 1 **Gender:** F
Reported: 25/01/2007 **Weight:** 1.90
Hospitalisation: **Age:** 0
Onset Date: 03/11/2006 **DOB:** 03/11/2006
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rectal haemorrhage	Caused or prolonged inpatient hospitalisation	Passing of blood stools more than 6-8 time the morning of 07/11/06	Mother ceased breast feeding, LHMSadministered IV, ticarcillin sodium and potassium devulanate. Parenteral nutrition

Medicine Details:

TACROLIMUS (Suspected) **Reason:**
4.0 Milligram Daily Breast milk transfer
Batch: **Started:** 03/11/2006 **Stopped:** 0

AZATHIOPRINE (Suspected) **Reason:**
50.0 Milligram Daily Breast milk transfer
Batch: **Started:** 03/11/2006 **Stopped:** 0

CEPHALEXIN (Suspected) **Reason:**
500.0 Milligram Daily Breast milk transfer
Batch: **Started:** 03/11/2006 **Stopped:** 0

PAROXETINE NOS (Suspected) **Reason:**
40.0 Milligram Daily Breast milk transfer
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother had breastfed infant for duration of baby's hospital stay (4 days since baby's birth).

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 225082 **Seq:** 1
Reported: 25/01/2007
Hospitalisation:
Onset Date: 03/11/2006
Outcome: Unknown

Gender: F
Weight: 1.90
Age: 0
DOB: 03/11/2006
Causality: Causality possible

Reaction Detail

Medicine Details:

OMEPRAZOLE (Suspected)			**Reason:**	
	20.0 Milligram	Daily		Breast milk transfer
Batch:	**Started:**		**Stopped:**	0
DILTIAZEM HYDROCHLORIDE (Suspected)			**Reason:**	
	180.0 Milligram	Daily		Breast milk transfer
Batch:	**Started:**		**Stopped:**	0

Laboratory Investigations:

Additional Information:

Mother had breastfed infant for duration of baby's hospital stay (4 days since baby's birth).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 225466 **Seq:** 1
Reported: 06/02/2007
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 54
DOB: 08/02/1952
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		tingling in face and numbness around lips.	
Dizziness		Attempted withdrawal of Aropax over two weeks. Experienced dizziness, severe irritability, extremely emotional, crying, needle like sensations in head, headaches, balance problems, dazed/spaced out sensations, sleeping difficulties, tingling in face and numbness around lips.	Tried the following : Prozac (no help) - Valium (increased irritability - no real improvement) - Tried a stronger medication same family as Valium, name of which I cannot recall (similar response as to Valium. ; Condition detriorated to such an extent I resumed full dose (20mg) of Aropax. Note: It took several weeks after resuming Aropax for my body to recover both
Irritability		severe	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 225466 **Seq:** 1
Reported: 06/02/2007
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 54
DOB: 08/02/1952
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability			
Balance disorder			
Crying			
Drug withdrawal syndrome			
Feeling abnormal			
Headache			
Sleep disorder			

Medicine Details:

AROPAX (Suspected) **Reason:** Depression

Tablet 20.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 225628 **Seq:** 1
Reported: 09/02/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 20/12/2006
Outcome: Recovered

Gender: F
Weight: 85.00
Age: 51
DOB: 14/08/1955
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Blood prolactin increased		Galactorroea with elevated prolactin	Ceased medication

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Batch: **Started:** L TERM **Stopped:** 0

ZOLOFT (Suspected) **Reason:** Anxiety neurosis

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 15/06/2006 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/02/2007	Prolactin				Normal prolactin 30/05/2006 Prolactin elevated 21/12/2006.

Additional Information:

Report Detail

Case Number: 226284 **Seq:** 1 **Gender:** F
Reported: 04/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: 30/06/2005 **DOB:** 20/08/1980
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Incapacity/disability		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Reducing Oral
Batch: **Started:** 04/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 226957 **Seq:** 1 **Gender:** F
Reported: 26/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Aggression Memory impairment		Was taking Stilnox every 3 hours with every Sinemet dose and 2 at night. During the day was very aggressive: assaulted her husband, smashed wine glasses, threw her phone at strangers and swore violently. Also had significant memory dysfunction but husband used this to his advantage to avoid people and keep her home.	

Medicine Details:

STILNOX (Interaction) **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 05/03/2006

SINEMET (Interaction) **Reason:** Paralysis agitans
8.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

SINEMET CR (Interaction) **Reason:** Paralysis agitans
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** Contin

AROPAX (Interaction) **Reason:** Depression
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 226957 **Seq:** 1 **Gender:** F
Reported: 26/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TRITACE (Other drug)			**Reason:**	Essential benign hypertension	
	2.5	Milligram	Daily		
Batch:	**Started:**	L TERM	**Stopped:**	Contin	
ZOTON (Other drug)			**Reason:**		
	30.0	Milligram	Daily		
Batch:	**Started:**	L TERM	**Stopped:**	Contin	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227415 **Seq:** 1 **Gender:** F
Reported: 10/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mobility decreased		Patient was unable to move, get changed	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has Parkinson disease.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227512 **Seq:** 1 **Gender:** F
Reported: 12/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Abnormal dreams Hyperhidrosis Insomnia Nausea		Patient experienced sweating, sleeplessness, vivid dreams and nausea. She then experienced severe hormonal changes and her periods stopped completely for three years and her weight doubled from 65kg to 130 kg.	

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AROPAX (Suspected) **Reason:** Anxiety neurosis
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227516 **Seq:** 1 **Gender:** F
Reported: 12/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Aggression Amenorrhoea Dizziness		Patient experienced drug withdrawl syndrome, nausea, vomiting, dizziness, hyperhidrosis, pyrexia, chills, tremor, insomnia, anorexia, vertigo, paraesthesia, confusional state, anxiety, irritability, panic attacks, mood swings, depression, suicidal ideation, aggression, fear, headaches, migraine, blurred vision, photosensitivity reaction, hyperacusis, hyperaesthesia, gastroenteritis, nightmare, muscle spasms, amenorrhoea, bruxism and syncope.	

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After a year, the subject was still not off paroxetine because of severe withdrawals.

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227516 **Seq:** 1
Reported: 12/04/2007
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms			
Nausea			
Panic attack			
Suicidal ideation			
Vision blurred			
Vomiting			

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

After a year, the subject was still not off paroxetine because of severe withdrawals.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227545 **Seq:** 1 **Gender:** F
Reported: 11/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response unexpecte Anxiety Dizziness		Since changing drug has experienced anxiousness, dizzy feeling in eyes.	Changed back to Paxtine

Medicine Details:

PAXTINE (Suspected) **Reason:**
Tablet Daily Oral
Batch: **Started:** 23/02/2007 **Stopped:** 16/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient has been on paroxeting for 13 years never experienced such symptoms previously.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227738 **Seq:** 1 **Gender:** F
Reported: 19/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Blood pressure increased		Patient experienced acute-onset arousal, agitation, disorganised behaviour and 2 episodes of generalised tonic clonic seizures. Over the next few days, examination revealed confusion, grandiose delusion, poor insight, slurred and pressured speech, and elated and labile affect. The patient also had neurological signs of myoclonic jerks of facial muscle, increased muscle tone and ankle clonus. She also experienced intermittent tachycardia, pupil dilation, increased body temperature (up to 38 degrees celsius) and increased blood pressure.	Valproic acid and olanzapine.

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression

Tablet 80.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain

Tablet 4.0 Dose Unspecified Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/04/2007	Creatine				Creatinine kinase level was elevated.
19/04/2007	Other data				Body temperature 38 degrees celcius

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227738 **Seq:** 1 **Gender:** F
Reported: 19/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Drug interaction Mania			

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression

Tablet 80.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain

Tablet 4.0 Dose Unspecified Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227789 **Seq:** 1 **Gender:** F
Reported: 20/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Was told to stop taking Aropax, within 24 hours was nauseaus, vomiting, dizzy and very unwell, headaches, tachycardia, anxiety, panic attacks, insomnia, uncontrollable emotions and anger	

Medicine Details:

AROPAX (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Over the course of the next 5 and a half years patient had several (6 or more) attempts to come off Aropax, all under the advise of differnet GP's with different methods.
Patient is currently down to 10mg of Aropax daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 227809 **Seq:** 1 **Gender:** F
Reported: 23/04/2007 **Weight:** 80.00
Hospitalisation: **Age:** 35Y
Onset Date: 08/03/2007 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Stomach discomfort Therapeutic response unexpecte Vertigo		Pateint experienced a consistently upset stomach and vertigo in relation to looking left and right, dangerous for driving, after taking a bio-equivalent generic drug.	Changed to Paxtine.

Medicine Details:

Oxetine (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Replaced with paxtine no further problem.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 228091 **Seq:** 1 **Gender:** U
Reported: 01/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Respiratory arrest	Death	Patient died and the cause of death was reported as acute respiratory arrest. Post mortem identified high paroxetine serum levels in the blood	
Drug level increased	Death		

Medicine Details:

AROPAX (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/05/2007	Autopsy report				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 228815 **Seq:** 1 **Gender:** F
Reported: 23/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonin syndrome, manic switch and drug interaction	
Abnormal behaviour	Caused or prolonged inpatient hospitalisation		
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation
200.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 228815 **Seq:** 1 **Gender:** F
Reported: 23/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood pressure increased	Caused or prolonged inpatient hospitalisation		
Clonus	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation
200.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 228815 **Seq:** 1 **Gender:** F
Reported: 23/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delusion of grandeur	Caused or prolonged inpatient hospitalisation		
Drug interaction	Caused or prolonged inpatient hospitalisation		
Dysarthria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation
200.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 228815 **Seq:** 1 **Gender:** F
Reported: 23/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Mania	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation
200.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 228815 **Seq:** 1 **Gender:** F
Reported: 23/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mydriasis	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation
200.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 228815 **Seq:** 1 **Gender:** F
Reported: 23/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation
200.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 228937 **Seq:** 1 **Gender:** F
Reported: 28/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 08/05/2007 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Hives first thing in the morning on both	

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 20.0 Milligram Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229081 **Seq:** 1 **Gender:** M
Reported: 30/05/2007 **Weight:** 73.00
Hospitalisation: **Age:** 65Y
Onset Date: 31/07/2002 **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	Increasing anxiety + agitation, Insomnia, abrupt change in personality, Suicide.	
Agitation	Death		
Anxiety	Death		

Medicine Details:

STILNOX (Interaction) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 05/06/2002 **Stopped:** 31/07/2002

AROPAX (Interaction) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229187 **Seq:** 1 **Gender:** M
Reported: 31/05/2007 **Weight:** 75.00
Hospitalisation: Required a visit to the doctor **Age:** 29
Onset Date: 31/05/2007 **DOB:** 28/11/1977
Outcome: Recovered 31/05/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		I took 10mg (half a tablet) for the first time, after being treated with the same chemical (but a different brand: Aropax) approximately four years earlier. After approximately 30-45 minutes, I felt first dizziness, then agitation and I was unable to sit still for approximately another 3 1/2	Advised by doctor to drink water and wait for symptoms to pass

Medicine Details:

PAXTINE (Suspected) **Reason:**
Tablet 10.0 Milligram 1 time Oral
Batch: X0143 **Started:** 31/05/2007 **Stopped:** 31/05/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229187 **Seq:** 1 **Gender:** M
Reported: 31/05/2007 **Weight:** 75.00
Hospitalisation: Required a visit to the doctor **Age:** 29
Onset Date: 31/05/2007 **DOB:** 28/11/1977
Outcome: Recovered 31/05/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Agitation		What I did not mention was that I had stopped taking St John's Wort 3 days earlier (the 10mg of paroxetine was taken at 10:30am on a Thursday, and the last tablet of St John's Wort that I had taken was either on the previous Sunday evening or Monday morning), as recommended by the pharmacist. After making the report (at which time the symptoms had subsided), I went to sleep but was twice awoken by fresh episodes of agitation, as well as nausea, shivering and headache. On talking to my doctor, she said that this was likely to be serotonin syndrome	Advised by doctor to drink water and wait for symptoms to pass

Medicine Details:

PAXTINE (Suspected) **Reason:**

Tablet 10.0 Milligram 1 time Oral

Batch: X0143 **Started:** 31/05/2007 **Stopped:** 31/05/2007

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229187 **Seq:** 1 **Gender:** M
Reported: 31/05/2007 **Weight:** 75.00
Hospitalisation: Required a visit to the doctor **Age:** 29
Onset Date: 31/05/2007 **DOB:** 28/11/1977
Outcome: Recovered 31/05/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restlessness			

Medicine Details:

PAXTINE (Suspected) **Reason:**

Tablet 10.0 Milligram 1 time Oral

Batch: X0143 **Started:** 31/05/2007 **Stopped:** 31/05/2007

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229309 **Seq:** 1 **Gender:** F
Reported: 05/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 42
Onset Date: 29/04/2007 **DOB:** 05/10/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Unintended pregnancy		Female patient experienced acute adominal pain and was rushed to the hospital. Diagnosed with unintended pregnancy	Pregnancy test performed was positive. Removal of Implanon Implant

Medicine Details:

PAROXETINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:**

IMPLANON IMPLANT (Interaction) **Reason:** Contraception
Implant 1.0 Dose Unspecified Cyclical Subcutaneous
Batch: **Started:** 15/02/2007 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/06/2007	Ultrasound				An ultrasound was unable to determine gestational age of the fetus

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229370 **Seq:** 1 **Gender:** F
Reported: 05/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Agitation Condition aggravated		At an unknown time after starting paroxetine hydrochloride, the patient became more anxious and agitated; her condition deteriorated	Paroxetine hydrochloride discontinued. Changed therapy to Venlafaxine

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 30.0 Milligram Daily Oral

Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Healy D et al. antidepressants and violence: problems at the interface of medicine and law. PLoS Medicine 2006; 3 (9) : 1478-1487.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229495 **Seq:** 1
Reported: 07/06/2007
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 45
DOB: 25/12/1961
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced drug interaction between Aropax and Dilantin and Serotonin Syndrome as a result of it.	
Drug interaction	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Interaction) **Reason:** Depression
Batch: **Started:** **Stopped:** 0

DILANTIN (Interaction) **Reason:** Depression
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229622 **Seq:** 1 **Gender:** M
Reported: 12/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 65Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Physical assault		In Feb 2003, patient had been arguing with his wife and she ahd temporarily moved out. He was treated with Aropax and Stilnox after she left. Three weeks later he physically assaulted her. He was waiting for her outside her work approx 8:30am and stabbed her 7 times and cut her throat. "Acted like a robot". He was jailed for 14 years but in May 05 they appealed and reduced sentence to 8 years. Wife was in hospital for 4 days	

Medicine Details:

STILNOX (Interaction) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 15/01/2003 **Stopped:** 0

AROPAX (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** 15/01/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No alcohol. No herbs.
Wife says her husband had no history of being violent. Absolutely uncharacteristic behaviour. Stilnox and Aropax were found on his person at time of incident.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 229624 **Seq:** 1 **Gender:** M
Reported: 12/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep walking	Caused or prolonged inpatient hospitalisation	In Aug 2005, patient reported that he had experienced lots of strange things on Stilnox - hallucinations, shaved hair off his chest, barricaded himself. But after getting quite drunk at a wedding, he came home and thought he went to bed. Apparantly, he was taking stilnox tablets in front of his sister, hallucinating "plants talking" and then she saw him tip over the balcony and fall to ground (2 floors). Fractured his face +++ wrists and shoulder. Also often hallucinated "little people" in his room and had conversations with them	Fractured face required metal plates in his cheeks and jaw.

Medicine Details:

ALCOHOL (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

STILNOX (Interaction) **Reason:**
Tablet 10.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

AROPAX (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Stilnox taken from 2000 - 2005.

Report Detail

Case Number: 229624 **Seq:** 1 **Gender:** M
Reported: 12/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face injury	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		
Hallucination	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ALCOHOL (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

STILNOX (Interaction) **Reason:**
Tablet 10.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

AROPAX (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:
Stilnox taken from 2000 - 2005.

Report Detail

Case Number: 229624 **Seq:** 1 **Gender:** M
Reported: 12/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Limb injury	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ALCOHOL (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

STILNOX (Interaction) **Reason:**
Tablet 10.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

AROPAX (Interaction) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:
Stilnox taken from 2000 - 2005.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 230201 **Seq:** 1 **Gender:** F
Reported: 21/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 19Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation	After taking the tablet, the patient felt unwell and had tremors and seizures. Patient was taken to hospital and went home few hours after	
Convulsion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GenRx Paroxetine (Suspected) **Reason:** Depression

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 30/05/2007 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 1998 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: AROPAX,GenRx Paroxetine,Oxetine,PAROXETINE HYDROCHLORIDE,PAROXETINE NOS,PAXTINE

Report Detail

Case Number: 230777 **Seq:** 1
Reported: 09/07/2007
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 62
DOB: 26/07/1944
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Alcohol use Anger Depressed mood Palpitations Tinnitus		Patient experienced withdrawal symptoms, including palpitations, increased alcohol consumption, tinnitus, anger and depressed mood	Aropax stopped.

Medicine Details:

AROPAX (Suspected) **Reason:** Anxiety neurosis

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 22/05/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information: