THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 171461 **Seq:** 1
Reported: 02/01/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 55.00
Age: 73
DOB: 28/04/1928
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Muscle spasms			Patient hospitalised.

Medicine Details:

LOSEC (Other drug) **Reason:** Other diseases of esophagus
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

ATACAND (Other drug) **Reason:** Essential benign hypertension
8.0 Milligram Daily
Batch: **Started:** 27/09/2001 **Stopped:** CONTIN

ZOLOFT (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 19/10/2001 **Stopped:** 13/12/2001

DAPA-TABS (Suspected) **Reason:** Essential benign hypertension
2.5 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:** 08/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for dapa-tabs is not accurate but indicates the drug was s tarted sometime in the year.

Report Detail

Case Number: 171601 **Seq:** 1
Reported: 09/01/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 12Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Platelet disorder		Resulting in increased bleeding time and	Patient was hospitalised. zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 3W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 171758 **Seq:** 1 **Gender:** M
Reported: 02/01/2002 **Weight:** 91.00
Hospitalisation: **Age:** 23
Onset Date: 28/09/2001 **DOB:** 17/08/1978
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability			
Dizziness			
Hallucination			Therapy changed back to venlafaxime. required a visit to doctor
Headache			
Muscle spasms			
Nausea			
Nightmare			

Medicine Details:

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:** Other disturbance of sensation
0.0 As necessary
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:** Otr spec symp psychopathol nec
0.0 As necessary
Batch: **Started:** L TERM **Stopped:**

SALBUTAMOL (Other drug) **Reason:** Asthma
0.0 As necessary
Batch: **Started:** L TERM **Stopped:**

METHADONE HYDROCHLORIDE (Other drug) **Reason:**
75.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 171758 **Seq:** 1

Reported: 02/01/2002

Hospitalisation:

Onset Date: 28/09/2001

Outcome: Recovered

Gender: M

Weight: 91.00

Age: 23

DOB: 17/08/1978

Causality: Causality probable

Reaction Detail

Medicine Details:

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

50.0 Milligram Daily

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 172187 **Seq:** 1 **Gender:** U
Reported: 25/01/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchospasm Cough Dyspnoea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 172232 **Seq:** 1 **Gender:** F
Reported: 25/01/2002 **Weight:**
Hospitalisation: **Age:** 75Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 172344 **Seq:** 1 **Gender:** U
Reported: 01/02/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchospasm Cough Dyspnoea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 172347 **Seq:** 1 **Gender:** F
Reported: 04/02/2002 **Weight:** 60.00
Hospitalisation: **Age:** 39
Onset Date: 21/01/2002 **DOB:** 13/09/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tongue oedema			Date of recovery 29/01/2002. required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 03/12/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced zolft on 50mg/d, and increased to 75mg/d on the 07/01/2002. stopped for 2 days on the 24/01/2002 and recommenced on lower dose of 50mg/d.

Report Detail

Case Number: 172379 **Seq:** 1
Reported: 01/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 27/01/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 57
DOB: 31/08/1944
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations			Patient was hospitalised. zoloft ceased.

Medicine Details:

PREDSOL (Other drug) **Reason:** Regional enteritis
Suppository 10.0 Milligram Daily Rectal
Batch: **Started:** **Stopped:** CONTIN

KLIOVANCE (Other drug) **Reason:** Menopausal symptoms
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

FERRO-GRADUMET (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** CONTIN

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 23/01/2002 **Stopped:** 28/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergies: sulpha, cephalexin and flagyl.

Report Detail

Case Number: 172379 **Seq:** 1
Reported: 01/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 27/01/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 57
DOB: 31/08/1944
Causality: Causality possible

Reaction Detail

Medicine Details:

PANAFCORT (Suspected)		**Reason:**	Regional enteritis
	25.0 Milligram	Daily	
Batch:	**Started:** 23/01/2002		**Stopped:**
DIPENTUM (Suspected)		**Reason:**	Regional enteritis
	1.0 Gram	Daily	
Batch:	**Started:** 22/01/2002		**Stopped:**

Laboratory Investigations:

Additional Information:

Allergies: sulpha, cephalexin and flagyl.

Report Detail

Case Number: 172425 **Seq:** 1
Reported: 06/02/2002
Hospitalisation:
Onset Date: 23/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 52.00
Age: 31
DOB: 28/05/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		Photosensitive type to face/neck red and	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

50.0 Milligram Daily

Batch: **Started:** 10/01/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 172432 **Seq:** 1 **Gender:** F
Reported: 06/02/2002 **Weight:** 68.00
Hospitalisation: **Age:** 15
Onset Date: 03/12/2001 **DOB:** 01/01/1986
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain Chest pain	Required Specialist Consultation	Complained of "bubbling in chest". Mild tenderness upper sternum.	Required a visit to doctor.

Medicine Details:

ECSTASY (M.D.M.A.) (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CANNABIS PREPARATION (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 30/11/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Amphetamine also suspected. patient took 2 zoloft instead of one.

Report Detail

Case Number: 172530 **Seq:** 1 **Gender:** F
Reported: 08/02/2002 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 21/01/2002 **DOB:** 07/02/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Life	Acute confusion.	
Hyponatraemia	Life	Severe hyponatraemia.	Monopril ceased. required a visit to doctor. reaction was life

Medicine Details:

MONOPRIL (Suspected) **Reason:** Essential benign hypertension
10.0 Milligram Daily
Batch: **Started:** 09/08/2000 **Stopped:** 22/01/2002

ZOLOFT (Suspected) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** 02/01/2002 **Stopped:** 22/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been on zoloft 50mg since july 1996.

Report Detail

Case Number: 172768 **Seq:** 1
Reported: 14/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 27/09/2001
Outcome: Recovered

Gender: F
Weight:
Age:
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Pateint was admitted to hospital, zoloft was ceased and sodium valproate was commenced

Medicine Details:

MICROGYNON (Other drug) **Reason:** Contraception
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 28/08/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electroencephalog				Eeg results were negative.

Additional Information:

Report Detail

Case Number: 172769 **Seq:** 1 **Gender:** F
Reported: 14/02/2002 **Weight:** 0.00
Hospitalisation: **Age:** 85Y
Onset Date: 19/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Neurosis			

Medicine Details:

LANOXIN (Other drug) **Reason:** Congestive heart failure
62.5 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 173460 is a duplicate.

Report Detail

Case Number: 172984 **Seq:** 1
Reported: 20/02/2002
Hospitalisation:
Onset Date: 17/11/2001
Outcome: Not yet recovered

Gender: M
Weight: 81.00
Age: 40
DOB: 06/10/1961
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia			Required a visit to doctor. change to efexor 75mg od. ck returned to normal.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

25.0 Milligram Daily

Batch: **Started:** 15/11/2001 **Stopped:** 27/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		10/01/2002	52	
	AST = SGOT		10/01/2002	74	
	Creatine		10/01/2002	885	

Additional Information:

Lower back, buttock and thight/hamstring muscle tiredness and stiffness.

Report Detail

Case Number: 173078 **Seq:** 1 **Gender:** F
Reported: 11/02/2002 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: 15/01/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Diarrhoea Nausea Vomiting			Zoloft ceased. date of recovery 20/01/02.

Medicine Details:

HYPERICUM 2000 + L-TYROSINE (Interaction) **Reason:** Depression
3.0 Dose Unspecified Daily
Batch: **Started:** 01/10/2001 **Stopped:** 14/01/2002

ZOLOFT (Interaction) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 15/01/2002 **Stopped:** 18/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 173114 **Seq:** 1 **Gender:** F
Reported: 25/02/2002 **Weight:**
Hospitalisation: **Age:** A2
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Auditory and visual hallucinations	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was taking zoloft 50mg for 4-5 months and still seemed depressed so dose of zoloft was increased to 100mg which caused symptoms, so patient went back to 50mg daily.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 173116 **Seq:** 1
Reported: 25/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/08/2001
Outcome: Recovered

Gender: M
Weight:
Age: 12Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura Bleeding time prolonged Platelet disorder		Bruising on left upper arm anf thigh.	Patient was hospitalised, zoloft was ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** S TERM **Stopped:** 19/09/1991

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Platelet function test on the 27 october 2001 showed abnormal platelet function with elevated collagen epinephrine aperture and elevated collagen adenosine diphosphate (adp) aperture. the pattern of platelet dysfunction is not aspirin related defect. platelet aggregation studies were normal

Additional Information:

The date of onset is not necessarily accurate but indicates onset was sometime in the month.

Report Detail

Case Number: 173192 **Seq:** 1 **Gender:** F
Reported: 25/02/2002 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: 27/08/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams		Vivid dreams.	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
100.0 Milligram Daily
Batch: **Started:** 01/06/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Same reaction occur nightly.

Report Detail

Case Number: 173460 **Seq:** 1 **Gender:** F
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 85Y
Onset Date: 19/12/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			Valium. zoloft stopped.

Medicine Details:

LANOXIN (Other drug) **Reason:** Congestive heart failure
Tablet 62.5 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 173527 **Seq:** 1 **Gender:** M
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 93
Onset Date: 25/02/2002 **DOB:** 30/01/1909
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Hallucination			Cease zoloft.

Medicine Details:

CORDARONE X 200 (Other drug) **Reason:** Otr&nos disord of heart rhythm
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

DISPRIN (Other drug) **Reason:** Other coagulation defects
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRITACE (Other drug) **Reason:** Essential benign hypertension
1.2 Milligram Daily
Batch: **Started:** **Stopped:**

UREMIDE (Other drug) **Reason:** Polyuria
80.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient allergic to penicillin.

Report Detail

Case Number: 173527 **Seq:** 1 **Gender:** M
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 93
Onset Date: 25/02/2002 **DOB:** 30/01/1909
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

FEBRIDOL (Other drug)			**Reason:**	Pain
	4.0	Gram	Daily	
Batch:	**Started:**			**Stopped:**
OROXINE (Other drug)			**Reason:**	Myxedema
	100.0	Microgram	Daily	
Batch:	**Started:**			**Stopped:**
KSR (Other drug)			**Reason:**	Unspec vitamin deficien states
	1.2	Gram	Daily	
Batch:	**Started:**			**Stopped:**
PANAFCORTELONE (Other drug)			**Reason:**	Otr mus rheum,fibrosit&myalgia
	25.0	Milligram	Daily	
Batch:	**Started:**	18/02/2002		**Stopped:** 26/02/2002

Laboratory Investigations:

Additional Information:

Patient allergic to penicillin.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 173527 **Seq:** 1 **Gender:** M
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 93
Onset Date: 25/02/2002 **DOB:** 30/01/1909
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 13/02/2002 **Stopped:** 26/02/2002

Laboratory Investigations:

Additional Information:

Patient allergic to penicillin.

Report Detail

Case Number: 173560 **Seq:** 1 **Gender:** F
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Nausea Serotonin syndrome			Metoclopramide.

Medicine Details:

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

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

ZOLOFT (Suspected) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** **Stopped:** 18M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 173590 **Seq:** 1 **Gender:** M
Reported: 07/02/2002 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Aggression			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 173620 **Seq:** 1
Reported: 14/03/2002
Hospitalisation:
Onset Date: 10/03/2002
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 34
DOB: 23/03/1967
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash morbilliform Pruritus		Rash face, chest, abdomen.	Required a visit to doctor.

Medicine Details:

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

ACTRAPID HM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** 01/03/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started on zoloft 25mg for 4 days then 50mg.

Report Detail

Case Number: 173660 **Seq:** 1
Reported: 14/03/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 67Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Nausea Vomiting			Patient hospitalised.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 173890 **Seq:** 1
Reported: 25/03/2002
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 79
DOB: 14/03/1923
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase in Myalgia Rhabdomyolysis			

Medicine Details:

NITROLINGUAL PUMPSPRAY (Other drug) **Reason:**
1.0 Dose Unspecified As necessary
Batch: **Started:** **Stopped:**

TENORMIN (Other drug) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Muscle biopsy				

Additional Information:

Previously on statins since 1991 - lipex. pravachol -> myalgia 1995. back on lipex until march 1997 - ceased while had pmr. the dose start date for lipitor is not accurate but indicates lipitor was started sometime in the year.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 173890 **Seq:** 1
Reported: 25/03/2002
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 79
DOB: 14/03/1923
Causality: Causality possible

Reaction Detail

Medicine Details:

MONOPLUS 10/12.5 (Other drug)			**Reason:**		
	1.0	Dose Unspecified	Daily		
Batch:	**Started:**			**Stopped:**	
NITRO-DUR (Other drug)			**Reason:**		
Cream	5.0	Milligram	Daily	Transdermal	
Batch:	**Started:**			**Stopped:**	
NORVASC (Other drug)			**Reason:**		
	2.5	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	
PANAMAX (Other drug)			**Reason:**		
	500.0	Milligram	Daily		
Batch:	**Started:**	L TERM		**Stopped:**	

Laboratory Investigations:

Additional Information:

Previously on statins since 1991 - lipex. pravachol -> myalgia 1995. back on lipex until march 1997 - ceased while had pmr. the dose start date for lipitor is not accurate but indicates lipitor was started sometime in the year.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 173890 **Seq:** 1
Reported: 25/03/2002
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 79
DOB: 14/03/1923
Causality: Causality possible

Reaction Detail

Medicine Details:

LIPITOR (Suspected)			**Reason:**	
	20.0 Milligram	Daily		
Batch:	**Started:** 01/01/1999		**Stopped:**	13/02/2002
ZOLOFT (Suspected)			**Reason:**	
	12.5 Milligram	Daily		
Batch:	**Started:** 30/01/2002		**Stopped:**	13/02/2002

Laboratory Investigations:

Additional Information:

Previously on statins since 1991 - lipex. pravachol -> myalgia 1995. back on lipex until march 1997 - ceased while had pmr. the dose start date for lipitor is not accurate but indicates lipitor was started sometime in the year.

Report Detail

Case Number: 173938 **Seq:** 1 **Gender:** F
Reported: 20/03/2002 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 01/05/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

CLOPIDOGREL (Other drug)			**Reason:**		
Tablet	75.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
TEMAZEPAM (Other drug)			**Reason:**		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
OMEPRAZOLE (Other drug)			**Reason:**		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
QUININE (Other drug)			**Reason:**		
Tablet	300.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Na = 125-128

Additional Information:

Abnormal cerebellar and neurological symptoms. ?paraneoplastic, but no neoplasm found.

Report Detail

Case Number: 173938 **Seq:** 1 **Gender:** F
Reported: 20/03/2002 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 01/05/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PREDNISONE (Other drug)			**Reason:**			
Tablet	0.0		Daily		Oral	
Batch:	**Started:**			**Stopped:**		CONTIN
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression		
Tablet	50.0	Milligram	Daily		Oral	
Batch:	**Started:**	L TERM		**Stopped:**		CONTIN

Laboratory Investigations:

Additional Information:

Abnormal cerebellar and neurological symptoms. ?paraneoplastic, but no neoplasm found.

Report Detail

Case Number: 173955 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/02/2002
Outcome: Recovered

Gender: F
Weight: 56.00
Age: 78Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Severe		Fluid restriction and treatment for uti. ceased rofecoxib, frusemide, sertraline.

Medicine Details:

UREMIDE (Suspected) **Reason:** Essential benign hypertension
40.0 Milligram Daily
Batch: **Started:** **Stopped:** 14/02/2002

VIOXX (Suspected) **Reason:** Pain
25.0 Milligram Daily
Batch: **Started:** **Stopped:** 14/02/2002

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 17/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	(135-145)	04/02/2002	106	
	Sodium	(135-145)	15/02/2002	109	
	Sodium	(135-145)	15/02/2002	107	
	Sodium	(135-145)	16/02/2002	114	
	Sodium	(135-145)	17/02/2002	123	
	Sodium	(135-145)	18/02/2002	124	
	Sodium	(135-145)	19/02/2002	130	

Additional Information:

Allergies: voltaren, penicillin-rash, tetox.

Report Detail

Case Number: 173955 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/02/2002
Outcome: Recovered

Gender: F
Weight: 56.00
Age: 78Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

UREMIDE (Suspected)			**Reason:**	Essential benign hypertension
	40.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	14/02/2002
VIOXX (Suspected)			**Reason:**	Pain
	25.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	14/02/2002
ZOLOFT (Suspected)			**Reason:**	Depression
	50.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	17/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	(135-145)	20/02/2002	130	
	Sodium	(135-145)	22/02/2002	132	
	Sodium	(135-145)	25/02/2002	134	

Additional Information:

Allergies: voltaren, penicillin-rash, tetox.

Report Detail

Case Number: 174023 **Seq:** 1 **Gender:** F
Reported: 28/03/2002 **Weight:**
Hospitalisation: **Age:** 49Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Accommodation disorder Visual disturbance Visual field defect			

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

0.0

Batch: **Started:** 01/10/1999 **Stopped:** 28/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start and stop date is not necessarily accurate but indicate the drug was started and stopped sometime in the month.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 174027 **Seq:** 1 **Gender:** M
Reported: 28/03/2002 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 174117 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 80Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Patient was hospitalised. bendrofluazide ceased. sodium levels are being carefully monitored

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred 2 weeks after commencement of zoloft. other medical conditions include hypertension.

Report Detail

Case Number: 174127 **Seq:** 1 **Gender:** F
Reported: 02/04/2002 **Weight:** 80.00
Hospitalisation: **Age:** 54
Onset Date: **DOB:** 25/10/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apnoea		Sleep apnoea.	
Weight increased		Weight gain of 2 stone over 1 year.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 174422 **Seq:** 1 **Gender:** F
Reported: 05/04/2002 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Dystonia Hypertonia Muscle twitching Serotonin syndrome Tetany		Tremor in arms, shoulders and neck, and	Ceased metoclopramide. treated with diazepam.

Medicine Details:

MAXOLON (Interaction) **Reason:** Nausea and vomiting
Injection 10.0 Milligram 2 times Intravenous
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

CELEBREX (Other drug) **Reason:**
400.0 Milligram Daily
Batch: **Started:** **Stopped:**

HYDROCORTISONE (Other drug) **Reason:**
4.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Creatinine kinase rose to 535 u/l.

Additional Information:

Two hours after the first dose of metoclopramide patient experienced symptoms, patient again was given metoclopramise 10mg iv and forty minutes later experienced similar symptoms again. metoclopramide was discontinued. two days later patient was mistakenly given metoclopramide10mg orally and 1.5 hours later experinced similar reaction. fisher aa, davis mw. serotonin syndrome caused by selective serotonin reuptake inhibitors-metoclopopramide interaction. ann pharmacother.2002 jan;36(1):67-71.

Report Detail

Case Number: 174422 **Seq:** 1 **Gender:** F
Reported: 05/04/2002 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Medicine Details:

MORPHINE SULPHATE (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Two hours after the first dose of metoclopramide patient experienced symptoms, patient again was given metoclopramise 10mg iv and forty minutes later experienced similar symptoms again. metoclopramide was discontinued. two days later patient was mistakenly given metoclopramide10mg orally and 1.5 hours later experinced similar reaction. fisher aa, davis mw. serotonin syndrome caused by selective serotonin reuptake inhibitors-metoclopopramide interaction. ann pharmacother.2002 jan;36(1):67-71.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 174441 **Seq:** 1
Reported: 11/04/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: A7
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Extreme sweating	Pateint was placed in hospital for observation, zoloft ceased.
Tremor		Extreme trembling	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Possible accidental drug overdose.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 174587 **Seq:** 1 **Gender:** F
Reported: 17/04/2002 **Weight:**
Hospitalisation: **Age:** 85
Onset Date: 07/03/2002 **DOB:** 17/12/1916
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Hepatitis	Life	Life threatening.	Date of recovery 21/03/2002. required a visit to doctor. tramal sr and zoloft ceased.

Medicine Details:

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

MYSOLINE (Other drug) **Reason:**
62.5 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

IMDUR (Other drug) **Reason:** Chron isch heart dis no hyper
60.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

TRAMAL SR (Suspected) **Reason:** Pain
400.0 Milligram Daily
Batch: **Started:** 21/02/2002 **Stopped:** 08/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT AST = SGOT Bilirubin				Alt 1651 Ast 2466 Bil 26

Additional Information:

The dose start date for the drug asasantin sr is not necessarily accurate but indicates the drug was started sometime in month.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 174587 **Seq:** 1 **Gender:** F
Reported: 17/04/2002 **Weight:**
Hospitalisation: **Age:** 85
Onset Date: 07/03/2002 **DOB:** 17/12/1916
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)		**Reason:** Depression	
	25.0 Milligram Daily		
Batch:	**Started:** 11/02/2002		**Stopped:** 08/03/2002
ASASANTIN SR (Suspected)		**Reason:**	
	2.0 Dose Unspecified Daily		
Batch:	**Started:** 01/10/2001		**Stopped:** 10/03/2002

Laboratory Investigations:

Additional Information:

The dose start date for the drug asasantin sr is not necessarily accurate but indicates the drug was started sometime in month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 174626 **Seq:** 1
Reported: 18/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 10/02/2002
Outcome: Recovered

Gender: F
Weight:
Age: 34
DOB: 16/10/1967
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Acute serotonin syndrome.	Patient was hospitalised. date of recovery: 23/2/2002.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** 30/01/2002 **Stopped:** 12/02/2002

TRAMAL SR (Suspected) **Reason:** Otr&unsp vertebrogen pain synd
400.0 Milligram Daily
Batch: **Started:** 07/01/2002 **Stopped:** 12/02/2002

TRAMAL (Suspected) **Reason:**
Injection 150.0 Milligram Daily Intramuscular
Batch: **Started:** 07/01/2002 **Stopped:** 12/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Serotonin syndrome with hyperreflexia/clonus, recurrent myoclonic jerks with short seizures and some memory deficit and confusion.

Report Detail

Case Number: 174634 **Seq:** 1 **Gender:** F
Reported: 16/04/2002 **Weight:** 63.00
Hospitalisation: **Age:** 41
Onset Date: 04/04/2002 **DOB:** 12/11/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Suicide attempt			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** 03/04/2002 **Stopped:**

REDUCTIL (Suspected) **Reason:** Headache
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 03/04/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 174639 **Seq:** 1 **Gender:** M
Reported: 18/04/2002 **Weight:**
Hospitalisation: **Age:** 75Y
Onset Date: 01/05/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

CLOPIDOGREL (Other drug)			**Reason:**		
Tablet	75.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
TEMAZEPAM (Other drug)			**Reason:**		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
OMEPRAZOLE (Other drug)			**Reason:**		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
QUININE (Other drug)			**Reason:**		
Tablet	300.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Na + 125-128 may 2001.

Additional Information:

Abnormal cerebella and neurological symptoms. ? paraneoplastic but no neoplasm found.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 174639 **Seq:** 1
Reported: 18/04/2002
Hospitalisation:
Onset Date: 01/05/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 75Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**		
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	29/06/2001
PREDNISONE (Suspected)			**Reason:**		
Tablet	0.0		Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Abnormal cerebella and neurological symptoms. ? paraneoplastic but no neoplasm found.

Report Detail

Case Number: 174670 **Seq:** 1 **Gender:** F
Reported: 19/04/2002 **Weight:**
Hospitalisation: Treated in outpatient department only. **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium			

Medicine Details:

ENALAPRIL MALEATE (Other drug) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:**

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

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 174720 **Seq:** 1
Reported: 22/04/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 70.00
Age:
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Life threatening reaction	Patient hospitalised.

Medicine Details:

COVERSYL (Other drug) **Reason:** Congestive heart failure
0.0
Batch: **Started:** L TERM **Stopped:**

LANOXIN (Other drug) **Reason:** Otr&nos disord of heart rhythm
0.0
Batch: **Started:** L TERM **Stopped:**

WARFARIN SODIUM (Other drug) **Reason:** Otr&nos disord of heart rhythm
0.0
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
0.0
Batch: **Started:** 10/02/2002 **Stopped:** 22/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Na = 108

Additional Information:

Report Detail

Case Number: 174992 **Seq:** 1
Reported: 01/05/2002
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
Syncope Dyspepsia	Severe	Severe syncope.	Patient was hospitalised. zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 175074 **Seq:** 1 **Gender:** U
Reported: 03/05/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Patient hospitalised.

Medicine Details:

ZOLOFT (Interaction) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

METOCLOPRAMIDE HYDROCHLORIDE (Interaction) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 175114 **Seq:** 1
Reported: 06/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 23/02/2002
Outcome: Recovered

Gender: F
Weight:
Age: 23
DOB: 07/01/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Aggression Agitation Grand mal convulsion Hallucination Paranoia		Total of 20 grand male seizers.	Treated with diazepam 40mg and phenytoin 1.5g. presented to hospital

Medicine Details:

MIRTAZAPINE (Interaction) **Reason:** Depression

30.0 Milligram Daily

Batch: **Started:** 24/01/2002 **Stopped:** 23/02/2002

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 23/02/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history - depression, post natal depression since 06/01, iv amphetamine user (says > 12 months ago), cannabis user (current).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 175123 **Seq:** 1 **Gender:** M
Reported: 06/05/2002 **Weight:**
Hospitalisation: **Age:** 87
Onset Date: 06/04/2002 **DOB:** 15/03/1915
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Sertraline ceased. no specific treatment required.

Medicine Details:

CAPADEX (Other drug) **Reason:** Pain
Capsule 2.0 Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:**

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

ALLOPURINOL (Other drug) **Reason:** Gout
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

QUININE (Other drug) **Reason:** Pain in limb
600.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		25/03/2002	138	
	Sodium		28/03/2002	134	
	Sodium		01/04/2002	132	
	Sodium		06/04/2002	131	
	Sodium		08/04/2002	126	
	Sodium		09/04/2002	127	
	Sodium		10/04/2002	128	

Additional Information:

Report Detail

Case Number: 175123 **Seq:** 1
Reported: 06/05/2002
Hospitalisation:
Onset Date: 06/04/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 87
DOB: 15/03/1915
Causality: Causality probable

Reaction Detail

Medicine Details:

OMEPRAZOLE (Other drug)				**Reason:**	Other diseases of esophagus	
	40.0	Milligram	Daily			
Batch:	**Started:**				**Stopped:**	
PANADEINE FORTE (Other drug)				**Reason:**	Pain	
Tablet	8.0	Dose Unspecified	Daily			Oral
Batch:	**Started:**				**Stopped:**	
MORPHINE SULPHATE (Other drug)				**Reason:**	Pain	
Injection	12.0	Milligram	Daily			Subcutaneous
Batch:	**Started:**				**Stopped:**	
SERTRALINE HYDROCHLORIDE (Suspected)				**Reason:**	Depression	
	50.0	Milligram	Daily			
Batch:	**Started:**	04/04/2002			**Stopped:**	10/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		11/04/2002	125	
	Sodium		13/04/2002	129	
	Sodium		17/04/2002	133	
	Sodium		19/04/2002	132	

Additional Information:

Report Detail

Case Number: 175228 **Seq:** 1 **Gender:** M
Reported: 07/05/2002 **Weight:**
Hospitalisation: **Age:** 81Y
Onset Date: 11/03/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		140/80 - 108/80.	

Medicine Details:

METOCLOPRAMIDE HYDROCHLORIDE (Other drug) **Reason:** Nausea and vomiting
Tablet 10.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:** CONTIN

BECLOMETHASONE DIPROPIONATE (Other drug) **Reason:**
400.0 Microgram Daily
Batch: **Started:** **Stopped:** CONTIN

ASASANTIN SR (Other drug) **Reason:**
Capsule 2.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** CONTIN

PANTOPRAZOLE (Other drug) **Reason:** Nausea and vomiting
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for atacand plus is not necessarily accurate but indicates the drug was started sometime in the month.

Report Detail

Case Number: 175228 **Seq:** 1 **Gender:** M
Reported: 07/05/2002 **Weight:**
Hospitalisation: **Age:** 81Y
Onset Date: 11/03/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PRAZOSIN HYDROCHLORIDE (Suspected)				**Reason:**	Essential benign hypertension
Tablet	1.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	11/02/2002
ATACAND PLUS 16/12.5 (Suspected)				**Reason:**	Essential benign hypertension
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**	01/11/2001		**Stopped:**	11/03/2002
VERAPAMIL HYDROCHLORIDE (Suspected)				**Reason:**	Essential benign hypertension
Tablet	240.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	11/03/2002
SERTRALINE HYDROCHLORIDE (Suspected)				**Reason:**	Depression
Tablet	25.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	13/03/2002

Laboratory Investigations:

Additional Information:

The dose start date for atacand plus is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 175228 **Seq:** 1 **Gender:** M
Reported: 07/05/2002 **Weight:**
Hospitalisation: **Age:** 81Y
Onset Date: 11/03/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

SIMVASTATIN (Suspected) **Reason:** Othr&unspec metabolic diseases

Tablet	10.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 13/03/2002

Laboratory Investigations:

Additional Information:

The dose start date for atacand plus is not necessarily accurate but indicates the drug was started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 175308 **Seq:** 1 **Gender:** M
Reported: 10/05/2002 **Weight:**
Hospitalisation: **Age:** 09Y
Onset Date: 09/04/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			Reduced zoloft dose to 1/4 x 50mg daily on 15.4.02, seemed to calm down a little by 17.4.02.

Medicine Details:

RISPERDAL (Other drug) **Reason:** Other atyp forms schizophrenia
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

ZOLOFT (Suspected) **Reason:** Depression
25.0 Milligram Daily
Batch: **Started:** 08/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prior to zoloft, the child was very depressed with threats of self harm with kitchen knives and threats to harm the family too, especially the mother. he threatened to "poison" her. patient not "acting like he's on speed", interested in everything, talking fast, ideas racing, vacuuming at 10pm.

Report Detail

Case Number: 175387 **Seq:** 1 **Gender:** M
Reported: 13/05/2002 **Weight:**
Hospitalisation: **Age:** 99Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anorexia Anxiety Confusional state Hallucination Hyponatraemia Insomnia			Drug was withdrawn slowly. date of recovery 29/04/02

Medicine Details:

SEDACALM (Other drug) **Reason:** Specific disorders of sleep
1.0 Dose Unspecified 1 time
Batch: **Started:** **Stopped:**

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

CLOPIDOGREL (Other drug) **Reason:**
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

CELEBREX (Other drug) **Reason:** Pain in joint
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking polytears, multivitamins.

Report Detail

Case Number: 175387 **Seq:** 1 **Gender:** M
Reported: 13/05/2002 **Weight:**
Hospitalisation: **Age:** 99Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Medicine Details:

PERSANTIN SR (Other drug)			**Reason:**	
	200.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
AMIODARONE HYDROCHLORIDE (Other drug)			**Reason:**	Otr&nos disord of heart rhythm
	200.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
PARACETAMOL (Other drug)			**Reason:**	Pain in joint
	3.0	Gram	Daily	
Batch:	**Started:**			**Stopped:**
OXAZEPAM (Other drug)			**Reason:**	Specific disorders of sleep
	15.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Additional Information:

Patient also taking polytears, multivitamins.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 175387 **Seq:** 1 **Gender:** M
Reported: 13/05/2002 **Weight:**
Hospitalisation: **Age:** 99Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
75.0 Milligram Daily
Batch: **Started:** **Stopped:** 02/04/2002

Laboratory Investigations:

Additional Information:

Patient also taking polytears, multivitamins.

Report Detail

Case Number: 175438 **Seq:** 1
Reported: 15/05/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypermagnesaemia			Patient was hospitalised.

Medicine Details:

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
0.0
Batch: **Started:** **Stopped:**

CELEBREX (Other drug) **Reason:** Unspecified arthritis
0.0
Batch: **Started:** **Stopped:**

LASIX (Other drug) **Reason:** Essential benign hypertension
0.0
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Magnesium levels are elevated.

Additional Information:

The dose start date for zoloft is not necessarily accurate but indictes the drug was started sometime in the month.

Report Detail

Case Number: 175438 **Seq:** 1
Reported: 15/05/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

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

Reaction Detail

Medicine Details:

ATACAND (Other drug)		**Reason:**	Essential benign hypertension
	0.0		
Batch:	**Started:**		**Stopped:**
FOSAMAX (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
ZOLOFT (Suspected)		**Reason:**	
	200.0 Milligram	Daily	
Batch:	**Started:** 01/12/2001		**Stopped:** CONTIN

Laboratory Investigations:

Additional Information:
The dose start date for zoloft is not necessarily accurate but indictes the drug was started sometime in the month.

Report Detail

Case Number: 175865 **Seq:** 1 **Gender:** M
Reported: 03/06/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion Drug level increased			

Medicine Details:

CLOZAPINE (Interaction) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Clopine levels were high, at 3.4 mmol/l.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 175923 **Seq:** 1 **Gender:** F
Reported: 04/06/2002 **Weight:** 80.00
Hospitalisation: **Age:** 37
Onset Date: 28/05/2002 **DOB:** 06/06/1964
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Bruise on limbs,purple bruise on upper	Zoloft ceased. required a visit to doctor.

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 27/03/2002 **Stopped:** 23/05/2002

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.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 175938 **Seq:** 1 **Gender:** F
Reported: 05/06/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 16/05/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Syncope			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176025 **Seq:** 1
Reported: 07/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 16/05/2002
Outcome: Recovered

Gender: M
Weight:
Age: A5
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle contractions involuntary Blood pressure fluctuation Abdominal pain Agitation Confusional state Dizziness Hyperhidrosis Serotonin syndrome Tremor		Clonus. Unstable blood pressure.	Aurorix and zoloft ceased. pateint was hospitalised. date of recovery 17/05/02.

Medicine Details:

AURORIX (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Interaction) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 16/05/2002 **Stopped:** 17/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also taking long list of herbal preparations (not specified). auorix ceased and the next day the patient was commenced on zoloft.

Report Detail

Case Number: 176025 **Seq:** 1
Reported: 07/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 16/05/2002
Outcome: Recovered

Gender: M
Weight:
Age: A5
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting			

Medicine Details:

AURORIX (Interaction) **Reason:**

0.0

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

ZOLOFT (Interaction) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 16/05/2002 **Stopped:** 17/05/2002

Laboratory Investigations:

Additional Information:

Also taking long list of herbal preparations (not specified). auorix ceased and the next day the patient was commenced on zoloft.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176032 **Seq:** 1
Reported: 07/06/2002
Hospitalisation: Hospitalisation prolonged
Onset Date: 28/03/2002
Outcome: Recovered with sequelae

Gender: F
Weight:
Age: 85Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Hyperanxiety-panic attacks.	Admitted to hospital. zoloft ceased. given efexor.
Tremor	Severe	Severe tremors.	
Anorexia			
Orthostatic hypotension			

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 01/03/2002 **Stopped:** 10D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Fall - sequelae. patient recovered with sequelae. patient takes numerous cardiac medications. 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 zoloft was start ed sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176156 **Seq:** 1 **Gender:** M
Reported: 11/06/2002 **Weight:** 53.00
Hospitalisation: **Age:** 84Y
Onset Date: 25/04/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Agitation Delirium		Generalised epilepsy.	Zoloft ceased.

Medicine Details:

OXAZEPAM (Other drug) **Reason:** Anxiety neurosis
30.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 01/03/2002 **Stopped:** 08/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium Radiololgy Sodium				K - 2.4. Ct showes single vessel disease and basal ganglion lacunae. Na - 128.

Additional Information:

The dose start date for zoloft is not necessarily accurate but indicates the drug was started sometime in the month. zoloft was started at 50mg (mar 02 - 25.4.02) then increased to 100mg (25.4.02 - 3.5.02) then increased to 150mg (3.5.02 - 8.5.02). sequelae: parkinsonism and risk of falling and exaggerated delirium due to large dose haloperidol.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176263 **Seq:** 1 **Gender:** F
Reported: 14/06/2002 **Weight:** 45.00
Hospitalisation: **Age:** 83
Onset Date: 28/03/2002 **DOB:** 06/04/1918
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176395 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:**
Hospitalisation: **Age:** 67Y
Onset Date: 07/08/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism		Sore jaw and aching teeth.	

Medicine Details:

SOMAC (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

MOTILIUM (Other drug) **Reason:**
3.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

UREMIDE (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking lamisil, stilnox, vioxx, panadeine forte, estraderm, gaviscon and artho-aid.

Report Detail

Case Number: 176395 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:**
Hospitalisation: **Age:** 67Y
Onset Date: 07/08/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

SPAN-K (Other drug)			**Reason:**	
	600.0	Milligram	Daily	
Batch:	**Started:**		**Stopped:**	
DIDROCAL (Other drug)			**Reason:**	
	1.0	Dose Unspecified	Daily	
Batch:	**Started:**		**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	Anxiety neurosis
	0.0	Milligram	1 time	
Batch:	**Started:**	30/07/2001	**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Patient also taking lamisil, stilnox, vioxx, panadeine forte, estraderm, gaviscon and artho-aid.

Report Detail

Case Number: 176430 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Speech disorder		Absent minded, mixed up words "drunk"	Date of recovery may 1999. zoloft ceased.

Medicine Details:

PROGESTERONE (Other drug) **Reason:** Otr&unspec ovarian dysfunction
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 01/10/1998 **Stopped:** 28/02/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for zoloft is not necessarily accurate but indicates the drug was started sometime in the month. zoloft ceased and behaviour improved "almost immediately", but stutter stayed for several months.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176508 **Seq:** 1
Reported: 20/06/2002
Hospitalisation:
Onset Date: 06/06/2002
Outcome: Not yet recovered

Gender: M
Weight: 69.00
Age: 32
DOB: 22/06/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Nausea			Patient required a visit to

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

50.0 Milligram Daily

Batch: **Started:** 05/06/2002 **Stopped:** 06/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176516 **Seq:** 1 **Gender:** F
Reported: 20/06/2002 **Weight:** 50.00
Hospitalisation: **Age:** 37
Onset Date: 07/03/2002 **DOB:** 06/12/1964
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Vertigo			Patient was required a visit to doctor. ceased zoloft.

Medicine Details:

ZANTAC (Other drug) **Reason:**
Oral application 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** 03/02/2002 **Stopped:** 09/04/2002

DIANE-35 ED (Other drug) **Reason:** Other diseases of esophagus
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 23/01/2002 **Stopped:** 18/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae - fall requiring 9 stitches to forehead (full thickness wound).

Report Detail

Case Number: 176519 **Seq:** 1 **Gender:** F
Reported: 21/06/2002 **Weight:** 80.00
Hospitalisation: **Age:** 29
Onset Date: 12/06/2002 **DOB:** 19/07/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Swelling of left ankle.	Date of recovery: 14/06/02.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 23/05/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 176713 **Seq:** 1
Reported: 01/07/2002
Hospitalisation:
Onset Date: 14/06/2002
Outcome: Not yet recovered

Gender: F
Weight: 49.00
Age: 16
DOB: 04/03/1986
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epistaxis			Patient was required to visit

Medicine Details:

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

Tablet 10.0 Milligram Daily Oral

Batch: **Started:** 12/06/2002 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 12/06/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had no history of nose bleeds. after increasing dose of zoloft from 25mg daily to 50mg patient developed about 8 nosebleeds each day.

Report Detail

Case Number: 176720 **Seq:** 1
Reported: 01/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/11/2001
Outcome: Not yet recovered

Gender: F
Weight: 71.00
Age: 69
DOB: 13/04/1932
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Dizziness Tremor	Severe	Severe headache started at back of head.	 Patient was hospitalised.

Medicine Details:

TRAMAL SR (Other drug) **Reason:** Pain
100.0 Milligram As necessary
Batch: **Started:** **Stopped:** CONTIN

VIOXX (Other drug) **Reason:** Unspecified arthritis
12.5 Milligram As necessary
Batch: **Started:** **Stopped:** CONTIN

INDERAL (Other drug) **Reason:** Migraine
80.0 Milligram Daily
Batch: **Started:** **Stopped:** 01/06/2002

LASIX (Other drug) **Reason:**
40.0 Milligram 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 onset sometime in the month.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176720 **Seq:** 1
Reported: 01/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/11/2001
Outcome: Not yet recovered

Gender: F
Weight: 71.00
Age: 69
DOB: 13/04/1932
Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 19/12/2000 **Stopped:** 03/04/2002

Laboratory Investigations:

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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176722 **Seq:** 1
Reported: 01/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 20/06/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 88
DOB: 18/02/1914
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Thirst			Patient was hospitalised. patient treated with iv fluids and demeclocycline 150mg q6h.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

SOLPRIN (Suspected) **Reason:**
150.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

NOTEN (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

COLOXYL (Suspected) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Sodium level: 110mmol/l

Additional Information:

During previous admissions (reasonss unknown) serum sodium has been low.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176722 **Seq:** 1
Reported: 01/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 20/06/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 88
DOB: 18/02/1914
Causality: Causality possible

Reaction Detail

Medicine Details:

CALTRATE (Suspected)			**Reason:**	
	2.0	Dose Unspecified	Daily	
Batch:	**Started:**	L TERM		**Stopped:**
IRBESARTAN (Suspected)			**Reason:**	
	150.0	Milligram	Daily	
Batch:	**Started:**	L TERM		**Stopped:**
AMARYL (Suspected)			**Reason:**	
	1.0	Milligram	Daily	
Batch:	**Started:**	L TERM		**Stopped:**

Laboratory Investigations:

Additional Information:

During previous admissions (reasonss unknown) serum sodium has been low.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176736 **Seq:** 1 **Gender:** F
Reported: 27/06/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/02/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Candidiasis			Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Never had thrush before started on 50mg got worse on 100mg, stopped on stopping zoloft. the date of onset is not necessarily accurate but indicates onset sometime in the month.

Report Detail

Case Number: 176840 **Seq:** 1 **Gender:** M
Reported: 13/06/2002 **Weight:**
Hospitalisation: **Age:** 99Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Drug withdrawal syndrome Insomnia			Sertraline withdrawn 25mg every 2 weeks.

Medicine Details:

OMEPRAZOLE (Other drug)			**Reason:**		
Oral application	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
CLOPIDOGREL (Other drug)			**Reason:**		
Oral application	75.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
CELEBREX (Other drug)			**Reason:**	Pain in joint	
Oral application	200.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PERSANTIN SR (Other drug)			**Reason:**	Otr&nos disord of heart rhythm	
Oral application	200.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking oxazepam, sedacalm, poly tears, multivitamins.

Report Detail

Case Number: 176840 **Seq:** 1 **Gender:** M
Reported: 13/06/2002 **Weight:**
Hospitalisation: **Age:** 99Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detai

Medicine Details:

AMIODARONE HYDROCHLORIDE (Other drug)			**Reason:**	Otr&nos disord of heart rhythm	
Oral application	200.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
PARACETAMOL (Other drug)			**Reason:**	Pain in joint	
	3.0	Gram	Daily		
Batch:	**Started:**			**Stopped:**	
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
	75.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	02/04/2002

Laboratory Investigations:

Additional Information:

Patient was also taking oxazepam, sedacalm, poly tears, multivitamins.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 176949 **Seq:** 1
Reported: 26/06/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diplopia Hallucination			Patient was hospitalised.

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recently had a cataract operation.

Report Detail

Case Number: 176977 **Seq:** 1 **Gender:** M
Reported: 08/07/2002 **Weight:** 70.00
Hospitalisation: **Age:** 51
Onset Date: 02/07/2002 **DOB:** 15/09/1950
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Insomnia		Early morning depression.	Zoton ceased. date of recovery 5.7.02.

Medicine Details:

ZOLOFT (Interaction) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** 10/05/2002 **Stopped:**

ZOTON (Interaction) **Reason:** Other diseases of esophagus
30.0 Milligram Daily
Batch: **Started:** 02/07/2002 **Stopped:** 04/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177074 **Seq:** 1
Reported: 08/07/2002
Hospitalisation:
Onset Date: 19/06/2002
Outcome: Not yet recovered

Gender: M
Weight: 84.00
Age: 65
DOB: 15/12/1936
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia Confusional state Pruritus Tremor			Required a visit to doctor.

Medicine Details:

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

ISOPTIN (Other drug) **Reason:**
180.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

VIOXX (Other drug) **Reason:**
12.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:**

ZOLOFT (Suspected) **Reason:**
100.0 Milligram Daily
Batch: **Started:** 01/10/2001 **Stopped:** 29/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for zoloft is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177074 **Seq:** 1
Reported: 08/07/2002
Hospitalisation:
Onset Date: 19/06/2002
Outcome: Not yet recovered

Gender: M
Weight: 84.00
Age: 65
DOB: 15/12/1936
Causality: Causality possible

Reaction Detail

Medicine Details:

TRAMAL (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 23/05/2002 **Stopped:** 29/06/2002

Laboratory Investigations:

Additional Information:

The dose start date for zoloft is not necessarily accurate but indicates the drug was started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177151 **Seq:** 1
Reported: 15/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 22/05/2002
Outcome: Recovered

Gender: F
Weight:
Age: 14Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Dose was reduced to 50mg daily. patient was hospitalised.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
150.0 Milligram Daily
Batch: **Started:** **Stopped:** 8W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had been on a increasing dose of zoloft since december 2001

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177154 **Seq:** 1 **Gender:** M
Reported: 15/07/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Patient was hospitalised. zoloft was ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis
150.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177155 **Seq:** 1 **Gender:** F
Reported: 15/07/2002 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Flushing Headache Hyperhidrosis Serotonin syndrome			Patient required a visit to

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
150.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 177202 **Seq:** 1 **Gender:** F
Reported: 16/07/2002 **Weight:** 54.00
Hospitalisation: **Age:** 66
Onset Date: 30/03/2002 **DOB:** 09/06/1935
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paralysis		Paralysis of the l arm	Date of recovery 4/4/02

Medicine Details:

VENTOLIN (Other drug) **Reason:** Asthma
Inhalation 0.0 As necessary Inhalation
Batch: **Started:** L TERM **Stopped:**

EVISTA (Other drug) **Reason:** Other diseases of bone
60.0 Milligram Daily
Batch: **Started:** 23/11/1999 **Stopped:**

OROXINE (Other drug) **Reason:** Thyrotoxicosis w/o ment goiter
0.1 Milligram Daily
Batch: **Started:** **Stopped:**

FLIXOTIDE (Other drug) **Reason:** Asthma
Inhalation 2.0 Dose Unspecified Daily Inhalation
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177202 **Seq:** 1
Reported: 16/07/2002
Hospitalisation:
Onset Date: 30/03/2002
Outcome: Recovered

Gender: F
Weight: 54.00
Age: 66
DOB: 09/06/1935
Causality: Causality probable

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
200.0 Milligram Daily
Batch: **Started:** 26/03/2002 **Stopped:** 30/03/2002

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177378 **Seq:** 1 **Gender:** M
Reported: 26/07/2002 **Weight:** 70.00
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 24/05/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Arthralgia Hyperhidrosis			Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 17/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177426 **Seq:** 1
Reported: 24/07/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 40.00
Age: 12Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysarthria Dyspnoea Dystonia Extrapyramidal disorder Hypertonia Muscle twitching		Difficulty in talking	Benztropine 0.02mg/kg

Medicine Details:

MORPHINE SULPHATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

TROPISETRON HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

METHYLPHENIDATE HYDROCHLORIDE (Suspected) **Reason:**
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Difficulty in talking, shortness of breath and difficulty moving because of st iffness. his speech was slurred and he was unable to close his mouth. the pati ent then began experiencing a twitching in his heands, shoulders, neck and hea d, which progressed to jerking movements of his jaw and arms. j.pediatr. child health (2002) 38, 95-97.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177426 **Seq:** 1
Reported: 24/07/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 40.00
Age: 12Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

RISPERIDONE (Suspected)			**Reason:**		
Oral application	2.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**		
	25.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Difficulty in talking, shortness of breath and difficulty moving because of st iffness. his speech was slurred and he was unable to close his mouth. the pati ent then began experiencing a twitching in his heands, shoulders, neck and hea d, which progressed to jerking movements of his jaw and arms. j.pediatr. child health (2002) 38, 95-97.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177464 **Seq:** 1 **Gender:** F
Reported: 11/07/2002 **Weight:**
Hospitalisation: **Age:** A2
Onset Date: 10/03/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death Neonatal disorder			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
25.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:** 2M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient taking zoloft 25mg/d for depression for about 2 months experienced a miscarriage.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177532 **Seq:** 1
Reported: 30/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/01/2002
Outcome: Not yet recovered

Gender: F
Weight: 100.00
Age: 40
DOB: 15/11/1961
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Life	Balcked out for 1 hour at home.	
Cyanosis	Life		Reactions were life threatening. patient was hospitalised. required a visit to doctor.

Medicine Details:

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

ZOLOFT (Suspected) **Reason:**
150.0 Milligram Daily
Batch: **Started:** 01/01/1999 **Stopped:** 01/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for zoloft is not necessarily accurate but indicates the drug was started sometime in the month. rechallenge zoloft on day 2 - another blackout. sequelae: headaches , tiredness and weight gain.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177570 **Seq:** 1 **Gender:** F
Reported: 31/07/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 14/01/1953
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Constipation Flatulence			

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 01/08/2001 **Stopped:** 18/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Drug positive rechallenged. the dose stat and stop dates are not necessarily accurate but indicates zoloft was started and stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177607 **Seq:** 1 **Gender:** M
Reported: 01/08/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			The patient was hospitalised. given antipsychotic
Neurosis			Very disruptive

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
200.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 177615 **Seq:** 1
Reported: 02/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/06/2002
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 84
DOB: 07/12/1917
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope		Blackouts and falls.	Zoloft ceased. given tramal, iv salin, fluid restriction and vulebuoplasty for crush fracture. patient hospitalised
Convulsion		Probable seizure.	
Confusional state			
Hyponatraemia			
Speech disorder			

Medicine Details:

CALTRATE (Other drug) **Reason:** Other diseases of bone
1.2 Milligram Daily
Batch: **Started:** 07/06/2002 **Stopped:** 27/06/2002

CLOPIDOGREL (Other drug) **Reason:**
75.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 07/06/2002 **Stopped:** 27/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		14/06/2002	119	Serum na.
	Sodium		29/07/2002	127	Serum na.

Additional Information:

Patient history - crush fracture l1

Report Detail

Case Number: 177634 **Seq:** 1 **Gender:** F
Reported: 05/05/2002 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 05/06/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Tongue disorder Bruxism		Head nodding. Tongue clicking.	Sertraline and metoclopramide ceased.

Medicine Details:

VENTOLIN NEBULES (Other drug) **Reason:** Asthma
1.0 Dose Unspecified As necessary
Batch: **Started:** 07/05/2001 **Stopped:**

CIPROFLOXACIN (Other drug) **Reason:**
Injection 400.0 Milligram Daily Intravenous
Batch: **Started:** 31/05/2001 **Stopped:**

CEFTAZIDIME (Other drug) **Reason:** Unspecified septicemia
Injection 2.0 Gram Daily Intravenous
Batch: **Started:** 31/05/2001 **Stopped:**

ATROVENT NEBULISING SOLUTION (Other drug) **Reason:** Asthma
4.0 Dose Unspecified Daily
Batch: **Started:** 07/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking digoxin, theophylline syrup and paracetamol.

Report Detail

Case Number: 177634 **Seq:** 1 **Gender:** F
Reported: 05/05/2002 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 05/06/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

PULMICORT (Other drug)			**Reason:** Asthma	
	2.0 Milligram		Daily	
Batch:	**Started:** 18/05/2001			**Stopped:**
OMEPRAZOLE (Other drug)			**Reason:**	
Oral application	40.0 Milligram		Daily	Oral
Batch:	**Started:** 24/05/2001			**Stopped:**
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:** Depression	
	50.0 Milligram		Daily	
Batch:	**Started:** 30/05/2001			**Stopped:** 06/06/2001
METOCLOPRAMIDE HYDROCHLORIDE (Suspected)			**Reason:** Nausea and vomiting	
Injection	40.0 Milligram		Daily	Intravenous
Batch:	**Started:** 21/05/2001			**Stopped:** 06/06/2001

Laboratory Investigations:

Additional Information:

Patient also taking digoxin, theophylline syrup and paracetamol.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 177921 **Seq:** 1 **Gender:** M
Reported: 12/08/2002 **Weight:** 80.00
Hospitalisation: **Age:**
Onset Date: 07/08/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Dry mouth			 Sertraline ceased.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 06/08/2002 **Stopped:** 09/08/2002

RISPERIDONE (Suspected) **Reason:** Unspecified psychosis
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 06/08/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178065 **Seq:** 1
Reported: 15/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/06/2002
Outcome: Unknown

Gender: M
Weight:
Age: 81
DOB: 12/05/1921
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Delirium Hypernatraemia			Patient admitted to hospital. date of death: 4.7.02.

Medicine Details:

CALTRATE (Other drug) **Reason:**
1.2 Gram Daily
Batch: **Started:** **Stopped:**

OSTELIN 1000 (Other drug) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

LASIX (Other drug) **Reason:**
20.0 Gram Daily
Batch: **Started:** **Stopped:**

KARVEA (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin		15/06/2002	34	
	Bilirubin		22/06/2002	61	
	Creatinine		15/06/2002	96	
	Creatinine		19/06/2002	84	
	Creatinine		22/06/2002	93	
	Creatinine		26/06/2002	126	
	Potassium		15/06/2002	3.7	

Additional Information:

Delerium apparently precipitated by change from moclobemide to zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178065 **Seq:** 1
Reported: 15/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/06/2002
Outcome: Unknown

Gender: M
Weight:
Age: 81
DOB: 12/05/1921
Causality: Causality possible

Reaction Detail

Medicine Details:

ISCOVER (Suspected)			**Reason:**		
Tablet	75.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	23/06/2002
PANADEINE FORTE (Suspected)			**Reason:**		
Tablet	8.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	14/06/2002
ZOLOFT (Suspected)			**Reason:**		
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**	07/06/2002		**Stopped:**	14/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium		19/06/2002	3.3	
	Potassium		22/06/2002	3.9	
	Potassium		26/06/2002	4.4	
	Sodium		15/06/2002	148	
	Sodium		19/06/2002	149	
	Sodium		22/06/2002	148	
	Sodium		26/06/2002	154	

Additional Information:

Delerium apparently precipitated by change from moclobemide to zoloft.

Report Detail

Case Number: 178065 **Seq:** 1
Reported: 15/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/06/2002
Outcome: Unknown

Gender: M
Weight:
Age: 81
DOB: 12/05/1921
Causality: Causality possible

Reaction Detail

Medicine Details:

CALTRATE (Other drug)			**Reason:**		
	1.2	Gram	Daily		
Batch:	**Started:**			**Stopped:**	
OSTELIN 1000 (Other drug)			**Reason:**		
	1.0	Dose Unspecified	Daily		
Batch:	**Started:**			**Stopped:**	
LASIX (Other drug)			**Reason:**		
	20.0	Gram	Daily		
Batch:	**Started:**			**Stopped:**	
KARVEA (Suspected)			**Reason:**		
Tablet	150.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	23/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		27/06/2002	155	
	Urea		15/06/2002	12.9	
	Urea		19/06/2002	8.6	
	Urea		22/06/2002	8.4	
	Urea		26/06/2002	18.5	
	Urea		26/06/2002	18.2	

Additional Information:

Delerium apparently precipitated by change from moclobemide to zoloft.

Report Detail

Case Number: 178065 **Seq:** 1
Reported: 15/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/06/2002
Outcome: Unknown

Gender: M
Weight:
Age: 81
DOB: 12/05/1921
Causality: Causality possible

Reaction Detail

Medicine Details:

ISCOVER (Suspected)			**Reason:**		
Tablet	75.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	23/06/2002
PANADEINE FORTE (Suspected)			**Reason:**		
Tablet	8.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**			**Stopped:**	14/06/2002
ZOLOFT (Suspected)			**Reason:**		
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**	07/06/2002		**Stopped:**	14/06/2002

Laboratory Investigations:

Additional Information:

Delerium apparently precipitated by change from moclobemide to zoloft.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178085 **Seq:** 1 **Gender:** F
Reported: 12/08/2002 **Weight:** 54.00
Hospitalisation: **Age:** 15
Onset Date: 19/07/2002 **DOB:** 01/10/1986
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Headache Muscle spasms Nausea			Patient required a visit to doctor. date of recovery: 30/7/02

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 06/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug positive rechallenge.

Report Detail

Case Number: 178185 **Seq:** 1 **Gender:** U
Reported: 06/02/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Changes in his mental state.	

Medicine Details:

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

KALETRA (Suspected) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:**

INDINAVIR SULFATE (Suspected) **Reason:**
Capsule 0.0 Oral
Batch: **Started:** **Stopped:**

RESCRIPTOR (Suspected) **Reason:** Hiv infection
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 178218 **Seq:** 1 **Gender:** M
Reported: 21/08/2002 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 27/06/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

COLOXYL WITH SENNA (Other drug) **Reason:**
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** CONTIN

IPRATROPIUM BROMIDE (Other drug) **Reason:**
Inhalation 2.0 Dose Unspecified Daily Inhalation
Batch: **Started:** **Stopped:** CONTIN

FLUTICASONE PROPIONATE-SALMETEROL XINAFOATE (Other drug **Reason:**
Inhalation 4.0 Dose Unspecified Daily Inhalation
Batch: **Started:** **Stopped:** CONTIN

SALBUTAMOL (Other drug) **Reason:**
Inhalation 4.0 Dose Unspecified Daily Inhalation
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was also taking amitriptyline, clonazeapm, triethoprim, hyoscine, heparin, paracetamol.

Report Detail

Case Number: 178218 **Seq:** 1 **Gender:** M
Reported: 21/08/2002 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 27/06/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detai

Medicine Details:

DIOCTYL SODIUM SULPHOSUCCINATE (Other drug)			**Reason:**		
Tablet	2.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
LACTULOSE (Other drug)			**Reason:**		
Oral Liquid	40.0	Millilitre	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
OMEPRAZOLE (Other drug)			**Reason:**		
Tablet	40.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
OXYCODONE HYDROCHLORIDE (Other drug)			**Reason:**		
Tablet	160.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

The patient was also taking amitriptyline, clonazeapm, triethoprim, hyoscine, heparin, paracetamol.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178218 **Seq:** 1 **Gender:** M
Reported: 21/08/2002 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 27/06/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

OXYBUTYNIN HYDROCHLORIDE (Other drug)			**Reason:**		
Tablet	10.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**		
Tablet	150.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

The patient was also taking amitriptyline, clonazeapm, triethoprim, hyoscine, heparin, paracetamol.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178380 **Seq:** 1 **Gender:** F
Reported: 27/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vulval disorder		Clitoris half to three quarters smaller.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patients history: patient had a stroke during/after triple bypass heart surgery.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178395 **Seq:** 1 **Gender:** F
Reported: 29/08/2002 **Weight:** 57.00
Hospitalisation: **Age:** 41
Onset Date: 22/07/2002 **DOB:** 10/02/1961
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Nausea Tremor Visual disturbance			Ceased tablets/medication.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 11/07/2002 **Stopped:** 24/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178406 **Seq:** 1 **Gender:** F
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Metrorrhagia			Patient required a visit to doctor. implanon removed.

Medicine Details:

IMPLANON IMPLANT (Suspected) **Reason:**
Implant 0.0 Subcutaneous
Batch: **Started:** 03/01/2002 **Stopped:** 20/08/2002

ZOLOFT (Suspected) **Reason:** Depression
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: implanon removed.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178655 **Seq:** 1 **Gender:** M
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 0.0 Daily Oral
Batch: **Started:** **Stopped:** 5W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 178693 **Seq:** 1 **Gender:** F
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia			

Medicine Details:

MERSYNDOL FORTE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

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

ZOLOFT (Suspected) **Reason:** Pain
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had a car accident prior to zoloft initiation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178797 **Seq:** 1 **Gender:** F
Reported: 06/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 01/06/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety Confusional state			Seroquel ceased, oxazepam and sertraline doses decreased. commenced olanzapine

Medicine Details:

ALENDRONATE SODIUM (Other drug) **Reason:** Other diseases of bone
Tablet 70.0 Milligram Weekly Oral
Batch: **Started:** **Stopped:** CONTIN

RAMIPRIL (Other drug) **Reason:** Essential benign hypertension
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

CALCIUM CARBONATE (Other drug) **Reason:** Other diseases of bone
Tablet 1.2 Gram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

SEROQUEL (Suspected) **Reason:** Unspecified psychosis
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 178797 **Seq:** 1 **Gender:** F
Reported: 06/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 01/06/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	23/04/2002
OXAZEPAM (Suspected)			**Reason:**	Disturbance of sleep	
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	23/04/2002

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178799 **Seq:** 1
Reported: 06/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 30/08/2002
Outcome: Recovered

Gender: F
Weight: 68.00
Age: 51
DOB: 18/05/1951
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope			Patient was hospitalised. recovered 30/8/02.

Medicine Details:

PANADEINE FORTE (Other drug) **Reason:**
Oral application 2.0 Dose Unspecified Daily Oral
Batch: **Started:** 30/08/2002 **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 30/08/2002 **Stopped:** 30/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 178826 **Seq:** 1 **Gender:** F
Reported: 09/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension			Required a visit to doctor.

Medicine Details:

ORAL CONTRACEPTIVE NOS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178860 **Seq:** 1 **Gender:** F
Reported: 11/09/2002 **Weight:** 70.00
Hospitalisation: **Age:** 22Y
Onset Date: 28/02/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Nightmare		12kg in 6 months.	Patient required a visit to doctor. discontinued drug.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/02/2002 **Stopped:** 28/08/2002

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 are not necessarily accurate but indicates the drug was started and stopped sometime in the month. report 178861 is a duplicate of this report.

Report Detail

Case Number: 178870 **Seq:** 1
Reported: 12/09/2002
Hospitalisation:
Onset Date: 28/01/2001
Outcome: Not yet recovered

Gender: F
Weight: 61.00
Age: 55
DOB: 24/10/1945
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Around the waist as large as a five cent	Patient required a visit to

Medicine Details:

MONOPLUS 20/12.5 (Suspected) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** L TERM **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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178900 **Seq:** 1 **Gender:** F
Reported: 01/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 20/01/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gait disturbance Asthenia Confusional state Hyponatraemia		Loss of mobility	Patient required a visit to doctor. zoloft ceased

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug) **Reason:** Otr spec symp psychopathol nec
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

DOTHIEPIN HYDROCHLORIDE (Other drug) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 02/01/2002 **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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178902 **Seq:** 1
Reported: 07/08/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 24
DOB: 23/09/1977
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased	Life	Lack of efficacy, heart palpitations, hearing voices, collapsed, serotinin syndrome, paranoia, psychosis and schizophrenia	All medications were stopped after the "arrest" and he was started on pethidine, oxycontin, baclofen and valium. He was in the regular part of the hospital for approximately 12 dyas and then was committed to the mental health unit.
Hallucination	Life		
Palpitations	Life		
Paranoia	Life		

Medicine Details:

ZOLOFT (Suspected)			**Reason:** Depression	
	25.0 Milligram		Daily	Oral
Batch:	**Started:**		**Stopped:**	
DEPTRAN (Suspected)			**Reason:**	
	75.0 Milligram		Daily	Oral
Batch:	**Started:**		**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	
	400.0 Milligram		Daily	
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was on Zoloft 400mg daily dose for approximately three to four weeks when he began to hear voices.
Once admitted, the hospital continued Zoloft but decreased the dose to 200mg daily for approximately the next three to four days.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178902 **Seq:** 1
Reported: 07/08/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 24
DOB: 23/09/1977
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Life		
Schizophreniform disorder	Life		
Serotonin syndrome	Life		
Syncope	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

DEPTRAN (Suspected) **Reason:**
75.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
400.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

The patient was on Zoloft 400mg daily dose for approximately three to four weeks when he began to hear voices.
Once admitted, the hospital continued Zoloft but decreased the dose to 200mg daily for approximately the next three to four days.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178903 **Seq:** 1
Reported: 07/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/11/1999
Outcome: Unknown

Gender: F
Weight:
Age: AD
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Alcohol intolerance Suicide attempt			Zoloft ceased. patient was hospitalised.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 0.0 Daily Oral

Batch: **Started:** 01/10/1999 L TERM **Stopped:** 28/10/2000

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 are 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 178964 **Seq:** 1
Reported: 11/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 12/04/2000
Outcome: Not yet recovered

Gender: F
Weight:
Age: 60Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis Asthenia Back pain Urinary incontinence	Life	A proximal limb myonecrosis (wheelchair	Admitted to hospital. zoloft discontinued.

Medicine Details:

PREMARIN (Other drug) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

THIAMINE (Other drug) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

TEMAZEPAM (Other drug) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

PARACETAMOL (Other drug) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Muscle biopsy				Muscle biopsy (date of test unspecified) demonstrated acute

Additional Information:

Patient also taking - levothyroxine. medical history includes bipolar affective disorder and hypothyroidism.

Report Detail

Case Number: 178964 **Seq:** 1
Reported: 11/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 12/04/2000
Outcome: Not yet recovered

Gender: F
Weight:
Age: 60Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

LITHIUM CARBONATE (Other drug)			**Reason:**		
Oral application	500.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
CHLORPROMAZINE HYDROCHLORIDE (Other drug)			**Reason:**		
Oral application	50.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:**	29/10/1998		**Stopped:**	04/12/2000

Laboratory Investigations:

Additional Information:

Patient also taking - levothyroxine. medical history includes bipolar affective disorder and hypothyroidism.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179069 **Seq:** 1 **Gender:** F
Reported: 16/09/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 14Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Patient hospitalised.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179094 **Seq:** 1 **Gender:** M
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			Required a visit to doctor.

Medicine Details:

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

METHADONE HYDROCHLORIDE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is the first of two sequences: 179095 seq 2.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179095 **Seq:** 1 **Gender:** M
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Hyperglycaemia Hypoglycaemia			Required a visit to doctor.

Medicine Details:

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

METHADONE HYDROCHLORIDE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patients blood glucose levels were not fully stabilised prior to zoloft therapy, but patients blood glucose leves fluctuated more often while receiving zoloft. this report is the second of two sequences: 179094 seq 1.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179100 **Seq:** 1
Reported: 18/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 74
DOB: 15/12/1927
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft therapy was ceased. patient hospitalised.

Medicine Details:

SOMAC (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

ZOCOR (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

IMDUR (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

CAPOTEN (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - gaviscon and atrovent inhaler.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179100 **Seq:** 1
Reported: 18/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 74
DOB: 15/12/1927
Causality: Causality possible

Reaction Detail

Medicine Details:

ASPIRIN (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
MS CONTIN (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
ENDONE (Other drug)		**Reason:**	
Tablet	0.0		Oral
Batch:	**Started:**		**Stopped:**
VIOXX (Other drug)		**Reason:**	
Tablet	0.0		Oral
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Patient also taking - gaviscon and atrovent inhaler.

Report Detail

Case Number: 179100 **Seq:** 1
Reported: 18/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 74
DOB: 15/12/1927
Causality: Causality possible

Reaction Detail

Medicine Details:

VENTOLIN (Other drug)				**Reason:**		
Inhalation	0.0					Inhalation
Batch:	**Started:**				**Stopped:**	
SERETIDE ACCUHALER NOS (Other drug)				**Reason:**		
Inhalation	0.0					Inhalation
Batch:	**Started:**				**Stopped:**	
QUININE (Other drug)				**Reason:**		
	0.0					
Batch:	**Started:**				**Stopped:**	
ZOLOFT (Suspected)				**Reason:**	Depression	
Tablet	150.0	Milligram	Daily			Oral
Batch:	**Started:**				**Stopped:**	29/07/2002

Laboratory Investigations:

Additional Information:

Patient also taking - gaviscon and atrovent inhaler.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179101 **Seq:** 1 **Gender:** M
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft therapy was ceased. required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Units not specified.

Additional Information:

Zoloft was also initiated at 25mg/daily.

Report Detail

Case Number: 179102 **Seq:** 1 **Gender:** U
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dehydration Hypernatraemia			Both zoloft and karvezide ceased. required a visit to doctor

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 6M

KARVEZIDE NOS (Suspected) **Reason:**
Tablet 150.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179103 **Seq:** 1 **Gender:** F
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Bruises on torso.	
Purpura		Bruises on torso.	Required a visit to doctor.
Palpitations		Heart palpitations.	
Rash maculo-papular		On face.	
Oedema peripheral		Swollen ankles and hands.	
Dyspnoea			
Extrasystoles			
Insomnia			
Orthostatic hypotension			
Visual disturbance			

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 400.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of examinatin which has shown abnormal heart beats, anoxeria, manic-depressive and suicide attempt with warfarin and exposure to the chicken pox virus. zoloft was initiated at 200mg/daily. sequelae: yes _ outcome-unknown.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179106 **Seq:** 1
Reported: 18/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Syncope			Admitted to hospital on 20/06/2002. zoloft ceased.

Medicine Details:

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

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Sodium 119 mmol/l.

Additional Information:

Patient also taking - antihypertensive drug.

Report Detail

Case Number: 179107 **Seq:** 1
Reported: 18/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 50Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome Neurosis			All medications withdrawn. patient hospitalised.

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 23/03/2002 **Stopped:** 04/04/2002

ZYPREXA (Suspected) **Reason:**
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Relevant history - mental retardation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179108 **Seq:** 1
Reported: 18/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age: 24Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Neurosis Syncope			Patient hospitalised. given haloperidol. zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 400.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report - 179108 is a sequence to 179109 and 179110. zoloft was taken at 50mg/daily and then titrated up to 400mg/daily.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179109 **Seq:** 1 **Gender:** M
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:** 24Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Drug withdrawal syndrome			Zoloft discontinued.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 400.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report - 179109 is a sequence of 179108 and 179110. zoloft was taken at 50mg/daily and then titrated up to 400mg/daily.

Report Detail

Case Number: 179133 **Seq:** 1
Reported: 19/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 74Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia Malaise Rash Syncope	Caused or prolonged inpatient hospitalisation		Hospitalisation, steroids, fentanyl withdrawn

Medicine Details:

FENTANYL TRANSDERMAL (Suspected) **Reason:** Pain
Drug delivery system, transde 0.0 Transdermal
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179137 **Seq:** 1 **Gender:** M
Reported: 07/08/2002 **Weight:**
Hospitalisation: **Age:** 84Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Jaundice			

Medicine Details:

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

HEPARIN SODIUM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ASASANTIN SR (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

OSTELIN 1000 (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		15/04/2002	187	
	Bilirubin		15/04/2002	60	
	GGT = SGGT =		15/04/2002	2325	
	SAP = ALP		15/04/2002	926	

Additional Information:

Report Detail

Case Number: 179137 **Seq:** 1 **Gender:** M
Reported: 07/08/2002 **Weight:**
Hospitalisation: **Age:** 84Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

FOSAMAX (Other drug)			**Reason:**		
	0.0				
Batch:	**Started:**			**Stopped:**	
CALTRATE (Other drug)			**Reason:**		
	0.0				
Batch:	**Started:**			**Stopped:**	
XALATAN (Other drug)			**Reason:**		
	0.0				
Batch:	**Started:**			**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179158 **Seq:** 1 **Gender:** F
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Micturition disorder		Difficulty in passing urine	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was also taking vitamins (unspecified) and oestrogen (unspecified)

Report Detail

Case Number: 179178 **Seq:** 1 **Gender:** M
Reported: 20/09/2002 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Syncope			

Medicine Details:

CODRAL FLU AND COLD TABLETS (Other drug) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Experienced blackouts and dizziness when the patient did not take the dose.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179197 **Seq:** 1 **Gender:** M
Reported: 23/09/2002 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: 07/09/2002 **DOB:**
Outcome: Recovered 10/09/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoaesthesia facial Hypoaesthesia	 Severe	Facial numbness and loss of facial	Zoloft therapy ceased. Required a visit to doctor.

Medicine Details:

CAMPRAL (Other drug) **Reason:** Alcoholic addiction
Tablet Oral
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:** Alcoholic addiction
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 02/09/2002 **Stopped:** 07/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 179248 **Seq:** 1 **Gender:** F
Reported: 15/07/2002 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 21/01/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vaginal haemorrhage			Zoloft was reduced from 100mg to 50mg.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 21/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179249 **Seq:** 1
Reported: 07/08/2002
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: AE
DOB:
Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hallucination		Auditory and visual hallucinations.	
Hypertonia		Bilateral foot drop with spasms in both feet.	
Hypertonia		Plantar flexion & inversion both ft with rigidity.	
Confusional state			
Dystonia			
Pyrexia			
Serotonin syndrome			Tramadol, sertraline, fludrocortisone, pericyazine were ceased. treated with benserazide/levodopa and botulinum.
Somnolence			

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**
Capsule 400.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This is a literature report from the australian prescriber, date 2002, edition 25, volume 1, page 19.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179249 **Seq:** 1
Reported: 07/08/2002
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: AE
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

PERICYAZINE (Other drug) **Reason:**

0.0

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

Laboratory Investigations:

Additional Information:

This is a literature report from the australian prescriber, date 2002, edition 25, volume 1, page 19.

Report Detail

Case Number: 179264 **Seq:** 1 **Gender:** F
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Cholelithiasis Diarrhoea Gastritis			Patient had a chlocysectomy in mar 2002. zoloft was withdrawn a downward titration for a duration of several weeks.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is a seq of 179265.

Report Detail

Case Number: 179265 **Seq:** 1 **Gender:** F
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Coordination abnormal Drug withdrawal syndrome		Electric sensation of limbs.	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Endoscopy and colonoscopy. the results that the patient's gastric lining was inflammed.

Additional Information:

History of gastritis. this report is a seq of 179264.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179266 **Seq:** 1
Reported: 18/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

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

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia Confusional state		Atypical movements.	Zoloft was ceased. patient was hospitalised.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179268 **Seq:** 1 **Gender:** F
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion		Gestation was between 16 to 20 weeks.	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Two previous spontaneous abortions. patient was initally taking 25mg once daily and the dose was increased to 25mg twice daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179301 **Seq:** 1 **Gender:** F
Reported: 20/09/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism		Multiple pulmonary emboli.	Patient was hospitalised. patient was also treated with warfarin. zoloft ceased then started at a lower dose of 100mg daily

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 150.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179330 **Seq:** 1 **Gender:** F
Reported: 23/09/2002 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Nausea			Patient required a visit to

Medicine Details:

ZOLOFT (Suspected) **Reason:** Unspecifid affective psychosis

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient increased the dose from 200mg (against the instructions of her doctor) to 400mg daily. the patient felt that dose was effective and was much happier on this dose. 179330 is the sequence of 179331.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179331 **Seq:** 1 **Gender:** F
Reported: 23/09/2002 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haemorrhage		Both ears.	
Myalgia		Easily bruised on her legs and body.	
Arthralgia			
Drug withdrawal syndrome			Patient required a visit to
Ear pain			
Palpitations			
Purpura			

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Unspecifid affective psychosis
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Last month the patient reduced her dose to 300mg daily and developed joint pains and heart palpitations in the last 2 months. 179331 is the sequence of 179330.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179338 **Seq:** 1 **Gender:** F
Reported: 23/09/2002 **Weight:** 71.00
Hospitalisation: **Age:** 39
Onset Date: 18/09/2002 **DOB:** 17/09/1963
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria Bronchospasm Chest pain Oedema		Red itchy welts all over the body.	Date of recovery 20/09/02. required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 17/09/2002 **Stopped:** 19/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179375 **Seq:** 1
Reported: 25/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 21/07/2002
Outcome: Recovered

Gender: F
Weight:
Age: 81
DOB: 14/06/1921
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Hyponatraemia Vomiting			Patient was hospitalised. recovered 31/7/02.

Medicine Details:

GLIMEPIRIDE (Other drug) **Reason:** Diabetes mellitus
4.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

DOMPERIDONE (Other drug) **Reason:** Nausea and vomiting
30.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

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

ASPIRIN (Other drug) **Reason:** Chron isch heart dis no hyper
100.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Potassium				K=5.2. cr=0.11
	Sodium		01/04/2001	132	Na=107
	Sodium		22/07/2002	107	Na=107
	Sodium		24/07/2002	120	Na=107
	Sodium		26/07/2002	125	Na=107
	Sodium		30/07/2002	125	Na=107
	Sodium		31/07/2002	124	Na=107

Additional Information:

The dose start date is not necessarily accurate but indicates sertraline was started sometime in the month. allergies sulphur, erythromycin, vitramycin, gluten, lanoxin, sudafed.

Report Detail

Case Number: 179375 **Seq:** 1
Reported: 25/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 21/07/2002
Outcome: Recovered

Gender: F
Weight:
Age: 81
DOB: 14/06/1921
Causality: Causality possible

Reaction Detail

Medicine Details:

AMLODIPINE (Other drug)			**Reason:**	Essential benign hypertension	
	5.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
CELEBREX (Other drug)			**Reason:**	Osteoarthritis	
	200.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	21/07/2002
VITAMIN PREPARATION COMPOUND (Other drug)			**Reason:**	Essential benign hypertension	
	1.0	Dose Unspecified	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
LASIX (Suspected)			**Reason:**		
Tablet	160.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

The dose start date is not necessarily accurate but indicates sertraline was started sometime in the month. allergies sulphur, erythromycin, vitramycin, gluten, lanoxin, sudafed.

Report Detail

Case Number: 179375 **Seq:** 1
Reported: 25/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 21/07/2002
Outcome: Recovered

Gender: F
Weight:
Age: 81
DOB: 14/06/1921
Causality: Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**	01/01/1999		**Stopped:**	21/07/2002
METFORMIN HYDROCHLORIDE (Suspected)			**Reason:**	Diabetes mellitus	
Tablet	1.0	Gram	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	21/07/2002

Laboratory Investigations:

Additional Information:

The dose start date is not necessarily accurate but indicates sertraline was started sometime in the month. allergies sulphur, erythromycin, vitramycin, gluten, lanoxin, sudafed.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179376 **Seq:** 1
Reported: 25/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 40.00
Age: 41
DOB: 08/06/1961
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Patient was hospitalised. ceased zoloft and fluconazole.

Medicine Details:

OSTELIN 1000 (Other drug) **Reason:**
1.0 Thousand Internat Daily
Batch: **Started:** L TERM **Stopped:**

PREDNISOLONE (Other drug) **Reason:**
25.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

LOSEC (Other drug) **Reason:** Other diseases of esophagus
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

VALTREX (Other drug) **Reason:**
500.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		30/07/2002	120	
	Sodium		06/08/2002	128	

Additional Information:

This report is a seq of 179380.

Report Detail

Case Number: 179376 **Seq:** 1
Reported: 25/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 40.00
Age: 41
DOB: 08/06/1961
Causality: Causality possible

Reaction Detail

Medicine Details:

PLAQUENIL (Other drug)			**Reason:**		
	100.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	
TRITACE (Other drug)			**Reason:**	Essential benign hypertension	
	2.5	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	
FLUCONAZOLE (Suspected)			**Reason:**	Moniliasis	
Capsule	200.0	Milligram	Daily		Oral
Batch:	**Started:**	31/07/2002		**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	31/07/2002

Laboratory Investigations:

Additional Information:
This report is a seq of 179380.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179437 **Seq:** 1 **Gender:** F
Reported: 27/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			Patient required a visit to doctor. zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 179513 **Seq:** 1
Reported: 02/10/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 50Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Pyrexia Rash Rash erythematous			Admitted to hospital. zoloft discontinued.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179555 **Seq:** 1 **Gender:** F
Reported: 03/10/2002 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

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

RISPERIDONE (Suspected) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 01/01/2001 **Stopped:** 01/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Over a number months (date unspecified), sodium dropped from an unspecified level to 126.

Additional Information:

The dose start and stop dates for risperidone are not accurate but indicates the drug was start and stopped somtime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179587 **Seq:** 1
Reported: 04/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/08/2002
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 13
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Headache			
Nausea			
Serotonin syndrome			Zoloft therapy was ceased and then restarted and there was no reocurrance of events have been experienced. patient was hospitalised.
Urinary incontinence			
Vomiting			

Medicine Details:

ECSTASY (M.D.M.A.) (Interaction) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Interaction) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

PARACETAMOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

RISPERIDONE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 179588 **Seq:** 1 **Gender:** F
Reported: 04/10/2002 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 28/06/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Confusional state Disturbance in attention Hallucination Insomnia Paranoia			Zoloft therapy was ceased and the events resolved. patient required a visit to doctor.

Medicine Details:

TRAMAL (Other drug) **Reason:** Pain
0.0
Batch: **Started:** **Stopped:**

TRAMAL SR (Other drug) **Reason:** Pain
0.0
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history: bipolar affective disorder, fibromyalgia. the onset date is not necessarily accurate but indicates onset sometime in the month. the dose start and stop date is not necessarily accurate but indicates zoloft was started and stopped sometime in the month.

Report Detail

Case Number: 179588 **Seq:** 1 **Gender:** F
Reported: 04/10/2002 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 28/06/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TRAMAL (Suspected)			**Reason:**		
	0.0				
Batch:	**Started:**			**Stopped:**	
CARBAMAZEPINE (Suspected)			**Reason:**		
	0.0				
Batch:	**Started:**			**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**	01/10/2000		**Stopped:**	28/07/2001

Laboratory Investigations:

Additional Information:

Medical history: bipolar affective disorder, fibromyalgia. the onset date is not necessarily accurate but indicates onset sometime in the month. the dose start and stop date is not necessarily accurate but indicates zoloft was started and stopped sometime in the month.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179589 **Seq:** 1 **Gender:** F
Reported: 04/10/2002 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Conjunctivitis Eye pain Headache Photophobia Pruritus			

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 04/09/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was initiated on zoloft 25mg once daily on 4/9/02, was then increased to 50mg and then to 75mg daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179590 **Seq:** 1 **Gender:** F
Reported: 04/10/2002 **Weight:** 23.00
Hospitalisation: **Age:** 6Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			
Headache			
Nausea			
Pyrexia			
Tachycardia			

Medicine Details:

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

Tablet 25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179643 **Seq:** 1 **Gender:** F
Reported: 04/10/2002 **Weight:**
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Insomnia		Hands and back of neck.	Zoloft was ceased.

Medicine Details:

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

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

ASASANTIN SR (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

MINIPRESS (Other drug) **Reason:**
4.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history of hypertension.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179643 **Seq:** 1
Reported: 04/10/2002
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age: 62Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet	25.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 23/09/2002

Laboratory Investigations:

Additional Information:

Patient history of hypertension.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179648 **Seq:** 1 **Gender:** F
Reported: 08/10/2002 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			Patient was required a visit to

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179670 **Seq:** 1 **Gender:** F
Reported: 10/10/2002 **Weight:** 75.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alcoholism Drug withdrawal syndrome		Intense craving for white wine and beer When returned to Zoloft cravings ceased and when later transferred to Cipramil,	

Medicine Details:

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179682 **Seq:** 1 **Gender:** M
Reported: 11/10/2002 **Weight:** 100.00
Hospitalisation: **Age:** 47
Onset Date: 28/07/2002 **DOB:** 20/02/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Rash		Intense itch on chest and back.	 Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Pain

Tablet 100.0 Milligram Weekly Oral

Batch: **Started:** 08/07/2002 **Stopped:** 06/08/2002

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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179700 **Seq:** 1
Reported: 16/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 01/04/2002
Outcome: Recovered

Gender: M
Weight:
Age: 55Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia			Patient was hospitalised.

Medicine Details:

ALCOHOL (Suspected) **Reason:**

0.0

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

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				Blood alcohol reading of 0.147.

Additional Information:

Patient had a car accident in april 2002. the date of onset is not necessarily acccurate but indicates onset sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179705 **Seq:** 1 **Gender:** M
Reported: 13/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Depression			Ceased zoloft.

Medicine Details:

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179715 **Seq:** 1 **Gender:** F
Reported: 04/10/2002 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Anxiety		Worsening of depression since increase in	Required a visit to doctor.

Medicine Details:

LIPITOR (Interaction) **Reason:** Othr&unspec metabolic diseases
Tablet 80.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Interaction) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 179715 **Seq:** 1 **Gender:** F
Reported: 04/10/2002 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

TEGRETOL (Other drug) **Reason:**

0.0

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179760 **Seq:** 1 **Gender:** F
Reported: 08/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 47
Onset Date: 15/02/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypothyroidism Syncope			

Medicine Details:

ZOLOFT (Interaction) **Reason:** Depression
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

THYROXINE SODIUM (Interaction) **Reason:** Myxedema
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

VIOXX (Other drug) **Reason:**
Tablet 0.0 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 in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179876 **Seq:** 1 **Gender:** F
Reported: 16/10/2002 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 25/09/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Experienced tight feelings.	Zoloft ceased. required a visit to doctor.
Headache		Weird head.	
Hot flush			

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179906 **Seq:** 1
Reported: 23/10/2002
Hospitalisation:
Onset Date: 05/10/2002
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 26
DOB: 25/11/1975
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain Galactorrhoea Hyperprolactinaemia			Required a visit to doctor. decreased zoloft dose over 8 days. started on 11.10.02.

Medicine Details:

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

OSTELIN 1000 (Other drug) **Reason:**
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

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

OROXINE (Other drug) **Reason:** Myxedema
50.0 Microgram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 179906 **Seq:** 1
Reported: 23/10/2002
Hospitalisation:
Onset Date: 05/10/2002
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 26
DOB: 25/11/1975
Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 179932 **Seq:** 1
Reported: 18/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/02/2002
Outcome: Unknown

Gender: F
Weight:
Age: 80Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Drug level increased Hyponatraemia			Zoloft ceased. dilantin withheld till levels normalised, iv saline.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 01/01/2001 **Stopped:** 13/02/2002

DILANTIN (Suspected) **Reason:** Convulsions

Capsule 500.0 Milligram Daily Oral

Batch: **Started:** 08/01/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level	(40-80 M/L)	13/02/2002	97	
	Sodium		13/02/2002	118	

Additional Information:

Zoloft dose was increased from 100mg/daily to 200mg/daily on the 04/02/02. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for the drug zoloft is not necessarily accurate but indicates the drug was started sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 179979 **Seq:** 1 **Gender:** F
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 82Y
Onset Date: 09/10/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain			
Dizziness	Severe		Patient required a visit to doctor. zoloft was discontinued.
Dry mouth			
Headache	Severe		
Hyperhidrosis			
Hypertension	Severe		
Pain			

Medicine Details:

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

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 07/10/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				(ecg) results did show any signs of a myocardial infarction however there was some evidence of ventricaular hypertrophy.

Additional Information:

Patient has a history of slight elevation of thyroid levels.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180033 **Seq:** 1
Reported: 12/09/2002
Hospitalisation:
Onset Date: 28/03/2002
Outcome: Not yet recovered

Gender: U
Weight: 50.00
Age: 67
DOB: 09/03/1935
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Partial loss of vision.	Patient required a visit to

Medicine Details:

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

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/03/2002 **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 date is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180038 **Seq:** 1
Reported: 24/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 11/07/2002
Outcome: Recovered

Gender: F
Weight:
Age: 35Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain Delirium Face oedema Psychotic disorder			Patient was hospitalised. zoloft discontinued.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 11/07/2002 **Stopped:** 11/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of anaphylactic reaction to morphine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180075 **Seq:** 1 **Gender:** F
Reported: 29/10/2002 **Weight:**
Hospitalisation: **Age:** 75
Onset Date: 28/07/2002 **DOB:** 30/12/1926
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Consciousness fluctuating Hyponatraemia Inappropriate antidiuretic hormon			Hypertonic saline given. indapamide and sertraline were ceased

Medicine Details:

PARACETAMOL (Other drug) **Reason:**
1.0 Gram As necessary
Batch: **Started:** **Stopped:**

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

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

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:** Essential benign hypertension
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum osmolality		28/07/2002	244	
	Serum osmolality		29/07/2002	250	
	Sodium		28/07/2002	117	111
	Sodium		29/07/2002	122	111
	Sodium		31/07/2002	130	111
	Sodium		05/08/2002	132	111
	Sodium		11/08/2002	135	111

Additional Information:

This report is a seq of 180076.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180075 **Seq:** 1 **Gender:** F
Reported: 29/10/2002 **Weight:**
Hospitalisation: **Age:** 75
Onset Date: 28/07/2002 **DOB:** 30/12/1926
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Urine osmolality		29/07/2002	745	

Additional Information:

This report is a seq of 180076.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180361 **Seq:** 1 **Gender:** F
Reported: 05/11/2002 **Weight:** 76.00
Hospitalisation: **Age:** 83
Onset Date: 30/10/2002 **DOB:** 16/09/1919
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Tetany Dystonia		Ms spasm. Started to have problem with opening her jaw.	Date of recovery: 01/11/02.

Medicine Details:

MOGADON (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

ZOCOR (Other drug) **Reason:**
40.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:**

TENORMIN (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 20/10/2002 **Stopped:** 30/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180412 **Seq:** 1
Reported: 07/11/2002
Hospitalisation: Admitted to hospital
Onset Date: 10/10/2002
Outcome: Recovered

Gender: M
Weight:
Age: 19
DOB: 06/01/1983
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia Oculogyration Convulsion Mydriasis		38.2 degrees. Eyes rolled up.	Patient required a visit to doctor and was hospitalised. periactin 4mg tds, iv midazolam & diazepam. date of recovery: 12/10/02.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Four weeks prior found unconscious. 1/52 ago presented to a & e for ? seizure. reaction description; myoclonus: convulsive jerk on both arms/legs continuing for several hours. jerky movements continued for the next 2/7 intermittently. patient history of chronic fatigue syndrome.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180467 **Seq:** 1
Reported: 11/11/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 80.00
Age: 24Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability			
Confusional state			
Dizziness			
Hallucination			
Headache			
Muscle spasms			
Nausea			
Nightmare			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Interaction) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Interaction) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CANNABIS PREPARATION (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: illicit drug user, with 3-4 pipes marijuana daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180467 **Seq:** 1
Reported: 11/11/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 80.00
Age: 24Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Thinking abnormal			Patient was hospitalised. treated with antipsychotic and was changed rapidly from sertraline back to venlafaxine.

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Interaction)			**Reason:**		
Oral application	0.0			Oral	
Batch:	**Started:**			**Stopped:**	
TRAMADOL HYDROCHLORIDE (Interaction)			**Reason:**		
Oral application	0.0			Oral	
Batch:	**Started:**			**Stopped:**	
ZOLOFT (Interaction)			**Reason:**		
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
CANNABIS PREPARATION (Other drug)			**Reason:**		
	0.0				
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

History: illicit drug user, with 3-4 pipes marijuana daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180506 **Seq:** 1 **Gender:** F
Reported: 08/11/2002 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 12/03/2002 **DOB:** 18/04/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Arthralgia Gravitational oedema Pruritus		Large lumps.	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180643 **Seq:** 1 **Gender:** F
Reported: 15/11/2002 **Weight:** 75.00
Hospitalisation: **Age:** 26
Onset Date: 23/04/2002 **DOB:** 26/07/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching Aggression Anxiety Dyspnoea Insomnia		Twitching right arm	Stopped zoloft. required a visit ot doctor. recovered 7/2.

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180646 **Seq:** 1
Reported: 15/11/2002
Hospitalisation:
Onset Date: 10/11/2002
Outcome: Not yet recovered

Gender: F
Weight: 45.00
Age: 95
DOB: 07/02/1907
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction			Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 10/09/2002 **Stopped:** 12/11/2002

MOBIC (Suspected) **Reason:** Unspecified arthritis

Tablet 7.5 Milligram Daily Oral

Batch: **Started:** 12/10/2002 **Stopped:** 12/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180692 **Seq:** 1 **Gender:** F
Reported: 15/11/2002 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: 31/12/1998 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased Abdominal pain Diarrhoea		Weight loss of 20kg.	

Medicine Details:

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

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report is a seq of 180693 and 180694. the onset date is not necessarily accurate but indicates onset was soemtime in the year. the dose start date is not necessarily accurate but indicates zoloft was started sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180693 **Seq:** 1
Reported: 15/11/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/12/1998
Outcome: Not yet recovered

Gender: F
Weight:
Age: 54Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Described as electric shocks to the head.	Patient was hsopitalised and zoloft was ceased.

Medicine Details:

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

THYROXINE SODIUM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 10/10/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking hrt (unspecified) the onset date is not necessarilly accurate but indicates onset sometime in the year. the dose start date is not necessarily accurate but indicates zoloft was started sometime in the year. this report is a seq of 180692 and 180694.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180694 **Seq:** 1
Reported: 15/11/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/12/1998
Outcome: Not yet recovered

Gender: F
Weight:
Age: 54Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			Ceased zoloft.

Medicine Details:

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

THYROXINE SODIUM (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking hrt (unspecified) the onset date is not necessarily accurate but indicates onset was sometime in the year. the dose start date is not necessarily accurate but indicates zoloft was started sometime in the year. this report is a seq of 180692 and 180693.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180714 **Seq:** 1 **Gender:** U
Reported: 17/12/2002 **Weight:** 69.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain: 50 kg to 69 kg from sometime in 1998 to 5 February 2002, ie 2.5 years. Has lost about 5 kg since stopping Zoloft	lots of exercise and a low food

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Weight gain between 50 to 69 kg over 2 1/2 years. Zoloft was also initiated at 50mg/bd in 1999 and 50mg/daily in 1999 to 2001.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180774 **Seq:** 1 **Gender:** F
Reported: 18/12/2002 **Weight:** 50.00
Hospitalisation: **Age:** 17
Onset Date: **DOB:** 07/12/1985
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Diarrhoea Dizziness Malaise		Taking 60 mg mirtazapine daily: trialled a test dose of 12.5 mg sertraline in combination. Two hours later felt unwell, nauseous, whoozy and had diarrhoea. This lasted several hours.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 12.5 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

MIRTAZAPINE (Interaction) **Reason:** Depression
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ORAL CONTRACEPTIVE NOS (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180918 **Seq:** 1 **Gender:** U
Reported: 20/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life	Paitnet who was taking Zoloft died from hyponatraemia around 7-8 months ago.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 180925 **Seq:** 1 **Gender:** F
Reported: 21/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Dizziness Somnolence		Patient developed tiredness in the last 3 to 4 weeks and has many dreams when asleep. Constantly tired and will sleep occasionally after lunch for one and a half hours (somnolence). Had an unexplainable fall a few weeks ago and feels dizzy when she stands up quickly (postural dizziness).	

Medicine Details:

INDERAL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

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

EVENING PRIMROSE OIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started Zoloft in May 2002

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 180990 **Seq:** 1 **Gender:** U
Reported: 23/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 59
Onset Date: **DOB:** 17/09/1943
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Priapism		2 weeks of priapism	Given Viagra.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset March 2001.

Report Detail

Case Number: 181067 **Seq:** 1 **Gender:** M
Reported: 03/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 64Y
Onset Date: 04/10/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium		Delirium	cease lignocaine,

Medicine Details:

LIGNOCAINE (Suspected) **Reason:**
Injection 288.0 Milligram Daily Intravenous
Batch: **Started:** 03/10/2002 **Stopped:** 04/10/2002

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 02/10/2002 **Stopped:** 05/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181191 **Seq:** 1
Reported: 08/01/2003
Hospitalisation: Admitted to hospital
Onset Date: 17/08/2002
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 15
DOB: 13/03/1987
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia Blood creatine phosphokinase in Malaise Myalgia Neuroleptic malignant syndrome		Fever, Malaise, Ck was elevated on 27/08/2002 at 402 but unnoticed until his admission in 04/11/2002 when Ck was 1963. Neuroleptic Malignant Syndrome. Myalgia.	Date hospitalised 04/11/02.

Medicine Details:

OLANZAPINE (Suspected) **Reason:** Unspecified psychosis
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

RISPERIDONE (Suspected) **Reason:** Unspecified psychosis
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 04/11/2002

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 04/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2003	Creatine	CK range	27/08/2002	402	
08/01/2003	Creatine	CK range	04/11/2002	1963	
08/01/2003	Creatine	CK range	06/11/2002	3553	

Additional Information:

The dose start and stop date for the drug Olanzapine - 01/02 and 10/02. Dose start date for Risperidone - 01/01and dose start date for Sertraline - 01/02. Despite 10 days of treatment, patient remains psychotic.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181308 **Seq:** 1 **Gender:** F
Reported: 09/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: 28/11/2002 **DOB:** 27/01/1965
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Anxiety		Seizure and uneasiness	Ceased Zoloft. Given intravenous valium.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181350 **Seq:** 1 **Gender:** M
Reported: 10/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: 26/10/2002 **DOB:** 16/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	Developed nausea, diarrhoea, dizziness shortness of breath, thight chest.	oxygen, was put on drip, aspirin
Flushing	Caused or prolonged inpatient hospitalisation	Possible serotonin reaction, felt warm, faint	
Syncope	Caused or prolonged inpatient hospitalisation	Sweating bradycardia of 30 BPM, heart rate of 70 BPM .	

Medicine Details:

AURORIX (Interaction) **Reason:**
Tablet 300.0 Milligram Oral
Batch: **Started:** **Stopped:** 22/10/2002 0

ZOLOFT (Interaction) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 26/10/2002 **Stopped:** 26/10/2002

VIOXX (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient cycled 45.5km

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181350 **Seq:** 1 **Gender:** M
Reported: 10/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: 26/10/2002 **DOB:** 16/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bradycardia	Caused or prolonged inpatient hospitalisation		
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Chest pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AURORIX (Interaction) **Reason:**
Tablet 300.0 Milligram Oral
Batch: **Started:** **Stopped:** 22/10/2002 0

ZOLOFT (Interaction) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 26/10/2002 **Stopped:** 26/10/2002

VIOXX (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:
Patient cycled 45.5km

Report Detail

Case Number: 181350 **Seq:** 1 **Gender:** M
Reported: 10/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: 26/10/2002 **DOB:** 16/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AURORIX (Interaction) **Reason:**
Tablet 300.0 Milligram Oral
Batch: **Started:** **Stopped:** 22/10/2002 0

ZOLOFT (Interaction) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 26/10/2002 **Stopped:** 26/10/2002

VIOXX (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:
Patient cycled 45.5km

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181476 **Seq:** 1 **Gender:** U
Reported: 13/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unrelated death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died one week later from cancer.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181497 **Seq:** 1 **Gender:** F
Reported: 13/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Anxiety		Insomnia, nocturnal anxiety	Zoloft administration was switched from evening dosing to morning administration and the events have resolved r

Medicine Details:

TRAMAL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181583 **Seq:** 1 **Gender:** F
Reported: 14/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 11Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia Agranulocytosis Aplastic anaemia		Neutropenia, agranulocytosis, anaemia aplastic	

Medicine Details:

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181656 **Seq:** 1
Reported: 15/01/2003
Hospitalisation: Admitted to hospital
Onset Date: 19/09/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Hallucinations and paranoid persecutory	
Insomnia		Patient developed sleeplessness, emotional lability, disorientation	Zoloft ceased.
Serotonin syndrome		Tachycardia, elevated blood pressure, mild tremor and increased muscle tone and low grade serotonin syndrome	
Affect lability			
Disorientation			
Hypertension			
Myoclonus			
Paranoia			

Medicine Details:

OXYCONTIN (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
40.0 Milligram Daily
Batch: **Started:** 28/08/2000 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 12/07/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions occured 14 days after the Zoloft dose was increased from 300mg per day to 400mg per day.

Report Detail

Case Number: 181656 **Seq:** 1
Reported: 15/01/2003
Hospitalisation: Admitted to hospital
Onset Date: 19/09/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 99U
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia Tremor			

Medicine Details:

OXYCONTIN (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
40.0 Milligram Daily
Batch: **Started:** 28/08/2000 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 12/07/2000 **Stopped:**

Laboratory Investigations:

Additional Information:

Reactions occured 14 days after the Zoloft dose was increased from 300mg per day to 400mg per day.

Report Detail

Case Number: 181712 **Seq:** 1 **Gender:** F
Reported: 15/01/2003 **Weight:** 36.00
Hospitalisation: **Age:** 15Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased Anorexia		Weight loss, anorexia	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Intraarterial
Batch: **Started:** **Stopped:** 08/11/2002

ZOLOFT (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 181911 **Seq:** 1 **Gender:** F
Reported: 22/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: 01/11/2002 **DOB:** 07/12/1985
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Chills Diarrhoea Malaise		Nausea, disoder, rigor, malaise	

Medicine Details:

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

Tablet 12.5 Milligram 1 time Oral

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

MIRTAZAPINE (Suspected) **Reason:** Depression

Tablet 60.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous reaction to Venlafaxine-anaphylactoid

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 181916 **Seq:** 1 **Gender:** M
Reported: 22/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 88Y
Onset Date: 16/12/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Hypotension Renal failure		Hypotension, Agranulocytosis, Renal	

Medicine Details:

CARDIZEM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LASIX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

VIOXX (Suspected) **Reason:** Unspecified arthritis
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 16/12/2002

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 16/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/01/2003	Neutrophils				
22/01/2003	White blood cells				

Additional Information:

Patient was also taking Quinine, Temazepam, Glyceryl Trinitrate

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182037 **Seq:** 1 **Gender:** M
Reported: 24/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased Drug ineffective		Therapeutic Inefficacy, 25 kg weight gain	Zoloft increased to 100mg daily due to inefficacy.

Medicine Details:

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

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182038 **Seq:** 1 **Gender:** M
Reported: 24/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Depression Fatigue Mood swings Nausea		Drug Withdrawal Syndrome, fatigue, nausea, mood swings and depressive symptoms	

Medicine Details:

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

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182042 **Seq:** 1 **Gender:** F
Reported: 24/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 41Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsions aggravated; increase in the incidence of seizures.	

Medicine Details:

KEPPRA (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

TOPAMAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:** contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient suffered a stroke post partum, has recovered with a residual problem of poorly controlled epilepsy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182074 **Seq:** 1 **Gender:** F
Reported: 28/01/2003 **Weight:** 72.00
Hospitalisation: **Age:** 40
Onset Date: 18/03/2002 **DOB:** 02/02/1962
Outcome: Recovered 09/11/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Night sweats	Severe	Night Sweats	

Medicine Details:

BREVINOR (Other drug) **Reason:** Contraception
Batch: **Started:** L TERM **Stopped:**

ACTRAPID (Other drug) **Reason:** Diabetes mellitus
100.0 Millilitre As necessary
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 08/03/2002 **Stopped:** 07/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient allergic to Ceftriaxone and Metronidazole - Diarrhoea and I.D.D.M.

Report Detail

Case Number: 182082 **Seq:** 1 **Gender:** F
Reported: 28/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: 09/12/2002 **DOB:** 08/09/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Spontaneous abortion, approximately 12 weeks after her last menstral period.	

Medicine Details:

FOLIC ACID (Suspected) **Reason:** Anxiety neurosis
Oral application Oral
Batch: **Started:** 23/10/2002 **Stopped:** contin

RISPERDAL (Suspected) **Reason:** Anxiety neurosis
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** contin

ZOLOFT (Suspected) **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** contin

ALPRAZOLAM (Suspected) **Reason:** Anxiety neurosis
Tablet 6.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 27/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/01/2003	Radiololgy				

Additional Information:

Risk factors - smoking, pregnent, maternal aunt had miscarriage. Patient's history - includes genital warts prior to pregnancy.

Report Detail

Case Number: 182082 **Seq:** 1
Reported: 28/01/2003
Hospitalisation:
Onset Date: 09/12/2002
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 25
DOB: 08/09/1977
Causality: Causality possible

Reaction Detail

Medicine Details:

PROPRANOLOL HYDROCHLORIDE (Suspected) **Reason:** Migraine

Oral application	40.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 24/10/2002

Laboratory Investigations:

Additional Information:

Risk factors - smoking, pregnent, maternal aunt had miscarriage. Patient's history - includes genital warts prior to pregnancy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182112 **Seq:** 1 **Gender:** M
Reported: 28/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 03/12/2002 **DOB:** 30/09/1947
Outcome: Recovered 07/01/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration	Required Visit to Doctor	Mouth ulcer	

Medicine Details:

INTAL (Other drug) **Reason:**
Batch: **Started:** L TERM **Stopped:**

FLIXOTIDE (Other drug) **Reason:**
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 14/12/2001 **Stopped:** 23/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182144 **Seq:** 1 **Gender:** M
Reported: 29/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 11
Onset Date: 21/11/2002 **DOB:** 18/09/1991
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Stevens-Johnson syndrome		Stevens Johnson Syndrome.	Zoloft and Vioxx ceased. Started on Panadol, Aciclovir IV, Maxides, Chlorsig eye drops, Roxithromycin (2 days later), Xylocaine viscous and Pethidine.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

VIOXX (Suspected) **Reason:** Pain in joint
Suspension 6.0 Millilitre 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182168 **Seq:** 1 **Gender:** F
Reported: 30/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: 14/12/2002 **DOB:** 10/12/1986
Outcome: Recovered 01/01/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration	Required Visit to Doctor	Severe mouth and tongue ulcerations	multivitamins, bonjela
Tongue ulceration	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 13/12/2002 **Stopped:** 16/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182173 **Seq:** 1 **Gender:** F
Reported: 30/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: 17/10/2002 **DOB:** 27/11/1950
Outcome: Recovered 09/01/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism	Required Visit to Doctor	Bruxism which settled 3 days after	

Medicine Details:

TENORMIN (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 17/10/2002 **Stopped:** 06/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182188 **Seq:** 1 **Gender:** F
Reported: 31/01/2003 **Weight:** 68.00
Hospitalisation: **Age:** 73
Onset Date: **DOB:** 14/03/1929
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia in an elderly female patient suffering congestive heart failure and on diuresis.	Zoloft ceased.

Medicine Details:

ASTRIX 100 (Other drug) **Reason:** Congestive heart failure
Capsule 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

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

OMEPRAZOLE (Suspected) **Reason:** Peptic ulcer nos w/o ment perf
20.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182188 **Seq:** 1
Reported: 31/01/2003
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: F
Weight: 68.00
Age: 73
DOB: 14/03/1929
Causality: Causality possible

Reaction Detail

Medicine Details:

PERINDOPRIL (Suspected) **Reason:** Congestive heart failure
4.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182223 **Seq:** 1 **Gender:** M
Reported: 03/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 75
Onset Date: **DOB:** 30/10/1927
Outcome: Recovered 13/01/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Required Visit to Doctor	Persistent diarrhoea up to 8 loose stools a	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 09/10/2002 **Stopped:** 10/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset 10/2002. Patient also taking cartia, inderal, lanoxin, lipitor, timpilo 4.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182268 **Seq:** 1 **Gender:** F
Reported: 03/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	Also suffered from dizziness.	
Abdominal pain	Caused or prolonged inpatient hospitalisation	Experienced cramps in stomach.	
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Later diagnosed with bowel obstruction.	Zoloft ceased. Surgery for 8 hrs

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Spinal cord tumor diagnosed before zoloft was commenced 6 years ago, hypertension, asthma.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182268 **Seq:** 1 **Gender:** F
Reported: 03/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased	Caused or prolonged inpatient hospitalisation	Weight decreased by 8 kg	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Spinal cord tumor diagnosed before zoloft was commenced 6 years ago, hypertension, asthma.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182474 **Seq:** 1 **Gender:** F
Reported: 06/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 16/11/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Anxiety Dizziness Reflux oesophagitis Vomiting		Patient experienced nausea, vomiting, dizziness, gastric reflux, and felt anxious.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 16/11/2002 **Stopped:** 23/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History includes nausea and vomiting while taking pethidine (unspecified) and morphine (unspecified), and the patient experienced an allergic rash to Keflex (cephalexin) and sulfur (unspecified). Patient also taking Nexium, Avapro HCT and Zyloprim.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182507 **Seq:** 1 **Gender:** U
Reported: 07/02/2003 **Weight:** 98.00
Hospitalisation: **Age:** 61
Onset Date: 15/02/2002 **DOB:** 16/02/1940
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Dysphagia, gagging, coughing.	Zoloft ceased.
Dysphagia	Required Specialist Consultation	Dysphagia, gagging, coughing.	Zoloft ceased.
Retching		Dysphagia, gagging, coughing.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 15/11/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Atacand Plus, Atenolol, Baclofen and Influenza Vaccine. Patient had multiple investigations and specialist review.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182531 **Seq:** 1
Reported: 07/02/2003
Hospitalisation: Admitted to hospital
Onset Date: 09/01/2003
Outcome: Not yet recovered

Gender: M
Weight: 50.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Grand mal ~ 2 hours convulsions	Given Dilantin and was

Medicine Details:

TEMAZEPAM (Other drug)			**Reason:**		
Oral application	10.0	Milligram	Total		Oral
Batch:	**Started:**			**Stopped:**	
WARFARIN SODIUM (Other drug)			**Reason:**		
Tablet	5.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
COLOXYL WITH SENNA (Other drug)			**Reason:**		
Tablet	4.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
ZOLOFT (Suspected)			**Reason:**		
Tablet	50.0	Milligram			Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

SCC R neck multiple exusion. Supposed to have meds

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182531 **Seq:** 1
Reported: 07/02/2003
Hospitalisation: Admitted to hospital
Onset Date: 09/01/2003
Outcome: Not yet recovered

Gender: M
Weight: 50.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

TRAMAL (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

SCC R neck multiple exusion. Supposed to have meds

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182566 **Seq:** 1
Reported: 10/02/2003
Hospitalisation: Admitted to hospital
Onset Date: 05/09/2002
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 44
DOB: 21/08/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Life	3 clinical features of serotonin syndrome.	
Hypotension	Life	Hypotension headaches, sore neck, acute deterioration, twitching/jerking	
Tachycardia	Life	Tachycardia, hallucinations, thinking abnormal, meningitis	
Drug level increased	Life		
Hallucination	Life		
Headache	Life		
Hypoglycaemia	Life		
Meningitis aseptic	Life		
Muscle twitching	Life		

Medicine Details:

TACROLIMUS (Interaction) **Reason:**

Batch: **Started:** **Stopped:** 0

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**

80.0 Milligram Daily

Batch: **Started:** **Stopped:** 10/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/02/2003	Microbiology				
10/02/2003	Serum drug level	6 - 10			

Additional Information:

Patient also taking OKT 3, Mycophenolate, prednisolone, ganciclovir, septrin, omeprazole, diltiazem, calcitriol, atenolol.

Report Detail

Case Number: 182566 **Seq:** 1
Reported: 10/02/2003
Hospitalisation: Admitted to hospital
Onset Date: 05/09/2002
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 44
DOB: 21/08/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neck pain	Life		
Thinking abnormal	Life		

Medicine Details:

TACROLIMUS (Interaction) **Reason:**

Batch: **Started:** **Stopped:** 0

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**

80.0 Milligram Daily

Batch: **Started:** **Stopped:** 10/09/2002

Laboratory Investigations:

Additional Information:

Patient also taking OKT 3, Mycophenolate, prednisolone, ganciclovir, septrin, omeprazole, diltiazem, calcitriol, atenolol.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182616 **Seq:** 1 **Gender:** F
Reported: 10/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 08/08/1958
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Agitation	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 04/09/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182737 **Seq:** 1
Reported: 11/02/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 61Y
DOB:
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorexia		Change in appetite	Patient checked into hospital to have these effects investigated and was di
Flushing		Hot flushes.	
Nausea		Nausea	
Tremor		Patient experienced shaking in the legs	Patient checked into hospital to have these effects investigated and was discharged later that day. Zoloft ceased.
Abdominal pain upper		Stomach pain	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 03/01/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient felt much better and took another dose. Felt the same adverse events although they were not as pronounced. Suspected Drug Positive Rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182797 **Seq:** 1 **Gender:** F
Reported: 12/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Systemic lupus erythematosus		Systemis lupus erythematosus	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

TEGRETOL (Suspected) **Reason:**
Oral application Dose Unspecified Oral
Batch: **Started:** **Stopped:**

LARGACTIL (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182802 **Seq:** 1 **Gender:** M
Reported: 12/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 38
Onset Date: 23/01/2003 **DOB:**
Outcome: Recovered 27/01/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		Myocardial infarction	Treatment to prevent blood clotting. Sent inserted into

Medicine Details:

KALMA (Suspected) **Reason:**
Tablet Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prescribed Zoton for heartburn and previous allergy to Tetracycline which gave him red blotches.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182827 **Seq:** 1 **Gender:** F
Reported: 13/02/2003 **Weight:** 49.00
Hospitalisation: **Age:** 89
Onset Date: 01/02/2003 **DOB:** 07/09/1913
Outcome: Recovered 06/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Increasing confusion, anxiety, restlessness	Zoloft and Avapro HCT withdrawn, fluid restriction.
Anxiety	Caused or prolonged inpatient hospitalisation		
Blood sodium decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FOSAMAX (Suspected) **Reason:** Osteoporosis
70.0 Milligram Weekly
Batch: **Started:** **Stopped:** 01/02/2003

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 01/02/2003

BETALOC (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 01/02/2003

AVAPRO HCT 300/12.5 (Suspected) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 01/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/02/2003	Sodium		01/02/2003	117	
13/02/2003	Sodium		06/02/2003	132	

Additional Information:

Patient also taking Temaze, Tramal SR, Diabex, Imdur and Amaryl.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182827 **Seq:** 1 **Gender:** F
Reported: 13/02/2003 **Weight:** 49.00
Hospitalisation: **Age:** 89
Onset Date: 01/02/2003 **DOB:** 07/09/1913
Outcome: Recovered 06/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restlessness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FOSAMAX (Suspected) **Reason:** Osteoporosis
70.0 Milligram Weekly
Batch: **Started:** **Stopped:** 01/02/2003

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 01/02/2003

BETALOC (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 01/02/2003

AVAPRO HCT 300/12.5 (Suspected) **Reason:** Essential benign hypertension
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 01/02/2003

Laboratory Investigations:

Additional Information:
Patient also taking Temaze, Tramal SR, Diabex, Imdur and Amaryl.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182846 **Seq:** 1
Reported: 13/02/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient treated for depression experienced an epileptic fit. Physician states the patient took Tramal post-operative while still taking Zoloft and experienced the event.	Tramal ceased.

Medicine Details:

TRAMAL (Suspected) **Reason:**

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

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 182863 **Seq:** 1 **Gender:** F
Reported: 13/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 18
Onset Date: 31/10/2002 **DOB:** 14/08/1984
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Required Visit to Doctor	12kg net gain in 3 months. F/ H paternal IDDM	

Medicine Details:

IMPLANON IMPLANT (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

F.G.F. (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183105 **Seq:** 1
Reported: 20/02/2003
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
Drug administration error	Caused or prolonged inpatient hospitalisation	Drug maladministration	
Intentional overdose	Caused or prolonged inpatient hospitalisation	Intentional drug overdose	
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonin syndrome	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 400.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183318 **Seq:** 1
Reported: 25/02/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 18
DOB: 25/04/1984
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Severe agitation and confusion, resulting in multiple attempts of suicide/self harm.	
Confusional state		Severe agitation and confusion, resulting in multiple attempts of suicide/self harm.	
Suicide attempt		Severe agitation and confusion, resulting in multiple attempts of suicide/self harm.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

There was no previous history of this type of self harm. Date of onset - 10/2002. Dose start date for Zoloft - 10/2002

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183501 **Seq:** 1
Reported: 27/02/2003
Hospitalisation: Admitted to hospital
Onset Date: 15/01/2003
Outcome: Recovered

Gender: F
Weight: 75.00
Age: 71Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast microcalcification		Calcification in the breast.	

Medicine Details:

CALTRATE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** Contin

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** Contin

FOSAMAX (Suspected) **Reason:**
Tablet 70.0 Milligram Weekly Oral
Batch: **Started:** 15/05/2002 **Stopped:** Contin

HYDRENE 25/50 (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2003	Other data				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183558 **Seq:** 1 **Gender:** F
Reported: 28/02/2003 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 23/11/2002 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Arrhythmia Brain oedema Convulsion		Antidiuretic hormone, secretetion fatal, brain swelling, seizures and cardiac arrhythemia	Resuscitation, midazolam, inotropes, IV steroids, and 1L normal saline with 20 meq potassium at a 4 hourly rate

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:**

CARBAMAZEPINE (Suspected) **Reason:**
Oral application
Batch: **Started:** **Stopped:**

RULIDE (Suspected) **Reason:** Otr respiratory systm diseases
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/02/2003	Computerised axial tomography				CT of the brain showed diffuse brain oedema (loss of sulci and gerey/white interface
28/02/2003	Other data				Glasgow coma scale of 3 when found and she was not breathing

Additional Information:

Relevant medical history icludes asthma, alcohol addiction, amblyopia, ulcerative oesophagitis, epilepsy, hiatus hernia, menorrhagia, hysterectomy and emphysema. Also taking prednisolone, omeprazole, temazepam, terbutaline, fluticasone/salmeterol, salbutamol and ipratropium. The brain oedema may also be secondary to the cardiac arrest or to a possible head trauma.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183574 **Seq:** 1 **Gender:** F
Reported: 30/01/2003 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: **DOB:** 10/12/1986
Outcome: Recovered 01/01/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor	Drug rash day 14 of medication	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 16/12/2002 **Stopped:** 30/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183616 **Seq:** 1 **Gender:** F
Reported: 03/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 90
Onset Date: 16/02/2003 **DOB:** 19/07/1912
Outcome: Recovered 23/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life	Severe Hyponatremia.	Zoloft ceased and given NaCl infusion.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/02/2003 **Stopped:** 19/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/03/2003	Sodium				

Additional Information:

Patient is also taking Lotensin, Glyncophage, Reminyl.
Patient started Zoloft dose at 25mg on 10.2.03, it was then increased to 50mg.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183620 **Seq:** 1 **Gender:** F
Reported: 03/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 79
Onset Date: 23/02/2003 **DOB:**
Outcome: Recovered 24/02/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	Nausea and vomiting.	Rehydration and antiemetic. Zoloft was ceased.
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 20/02/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had two doses prior to onset of symptoms.
Patient also taking Panadeine Forte, Betaloc, Losec, Prednisone, Adalat, Frusemide and FGF.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183630 **Seq:** 1 **Gender:** F
Reported: 03/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Patient experienced liver dysfunction which progressively worsened.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183672 **Seq:** 1 **Gender:** F
Reported: 03/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 01/02/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Insomnia Restlessness		Excessive sweating, restlessness and	Tramal ceased.

Medicine Details:

TRAMAL SR (Interaction) **Reason:** Unspecified arthritis
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 03/12/2002 **Stopped:**

ZOLOFT (Interaction) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: Contin **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is also taking Zocor, Losec, and Temaze.
Date of recovery Feb 03.
Tramal SR stopped Feb 03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 183814 **Seq:** 1 **Gender:** M
Reported: 07/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 75
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased Anorexia Dizziness Flushing		Weight loss of 3 stone (19.05kg), loss of appitite, dizziness and facial flushing.	

Medicine Details:

SERC (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PEPCIDINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Avapro, Imdur, Zocor, Betaloc.

Report Detail

Case Number: 183873 **Seq:** 1
Reported: 10/03/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 36
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonin syndrome.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 184060 **Seq:** 1 **Gender:** F
Reported: 13/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 14/02/1995 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Anxiety Dizziness Malaise		Insomnia, dizziness, malaise and anxiety.	Zoloft was decreased to 100mg/day and then ceased Zoloft on 14/2/03

Medicine Details:

STELAZINE (Other drug) **Reason:** Unspecified psychosis
Batch: **Started:** L TERM **Stopped:**

LITHIUM CARBONATE (Other drug) **Reason:**
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 14/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking: Stelazine, Lithium, Oroxine and Somac.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184226 **Seq:** 1 **Gender:** F
Reported: 21/03/2003 **Weight:** 63.00
Hospitalisation: **Age:** 26
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Schizophreniform disorder Thought insertion		Schizophreniform disorder. Patient frightened and running away - was getting thought insertion about killing her children.	Sertraline ceased and given Risperdal.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

All patients with asperger disorder react idiosyncratically to psychotropic drugs.
Patient history: Gross hallucinogenic reaction some years ago to Aropax.
Patient also taking occasional Pulmicort and Panadol and rare Ibuprofen.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184296 **Seq:** 1
Reported: 21/03/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 27
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	Zoloft (sertraline) 50mg was commenced and the patient experienced increased agitation with obsessional violent thoughs. The patient was taking no other medication, Zoloft therapy was ceased and the agitation settled.	
Obsessive thoughts	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 184296 **Seq:** 1
Reported: 21/03/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 27
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Violent ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184344 **Seq:** 1 **Gender:** U
Reported: 24/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 15/10/2001 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asphyxia Convulsion		Seizure and asphyxia.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patients history: Initial (11 Mar 03) - epilepsy (present) - psychosis.
Patient also takes anticonvulasnts.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184478 **Seq:** 1 **Gender:** F
Reported: 28/03/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 23/12/2002 **DOB:**
Outcome: Recovered 10/02/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Crying Back pain Drug withdrawal syndrome Irritability Tremor		Breast feeding but poorly, at one week started to cry, shake, backache and irritable? reflux but didn't settle on medication, put to bottle but became worse.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft withdrawal started to bottlefeed. Mother on Zoloft during pregnancy. Mother on Zoloft while breastfeeding baby. Baby experienced withdrawal reaction upon cessation of breastfeeding.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184690 **Seq:** 1
Reported: 07/04/2003
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
Hypertension		Hypertenson.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184782 **Seq:** 1 **Gender:** F
Reported: 08/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 80Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation	Rash	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184844 **Seq:** 1 **Gender:** F
Reported: 09/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 85
Onset Date: 15/02/2002 **DOB:** 20/03/1916
Outcome: Recovered 12/03/2002 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Required Visit to Doctor	Developed postural hypotension and hyponatraemia shortly after starting Zoloft for depression.	Ceased Zoloft
Hyponatraemia	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 11/02/2002 **Stopped:** 01/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Ptient was also taking Avapro HCT, Losec, Ducene.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184884 **Seq:** 1
Reported: 10/04/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 33Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tension headache	Severe	Sever tension headaches.	Given Morphine

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 184885 **Seq:** 1
Reported: 10/04/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 83Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatremia	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 23/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 185078 **Seq:** 1
Reported: 14/04/2003
Hospitalisation: Required a visit to the doctor
Onset Date: 28/12/2002
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 54Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred		Blurred vision.	
Pain		Body aches	Trying to wean Xanax.
Burning sensation		Right arm felt numb and tingly, face felt burning sensation.	
Pain		Right leg and right side of body appeared to have sharp pain.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Unspecifid affective psychosis

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 27/12/2002 **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Xanax, Zocor, Norvasc, Vioxx and Losec.

Report Detail

Case Number: 185111 **Seq:** 1
Reported: 17/04/2003
Hospitalisation: Admitted to hospital
Onset Date: 13/03/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 79
DOB: 08/01/1924
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swollen tongue Facial palsy Rash pruritic Swelling face		Tongue swelling, facial swelling, facial droop, pruritic rash.	Phenergan (Promethazine HCL) injection (dose unspecified). Zoloft ceased

Medicine Details:

TELMISARTAN (Other drug) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 16/05/2002 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 05/02/2003 **Stopped:** 13/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Micardis therapy was ceased and the patient rechallenged and no symptom recurrence (unspecified) occurred. The patient was not rechallenged with Zoloft.
Patient history: Hypertension (present) and open angle glaucoma (present).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185114 **Seq:** 1
Reported: 17/04/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 73Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Cataract Otitis media Vision blurred		Dizziness, blurred vision, cataract extraction, middle ear infection.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Dilantin and Tegretol.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185194 **Seq:** 1
Reported: 23/04/2003
Hospitalisation:
Onset Date: 15/02/2003
Outcome: Not yet recovered

Gender: F
Weight: 130.00
Age: 38
DOB: 01/08/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema nodosum	Required Visit to Doctor	Erythema nodosum.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/04/2003	LDH				

Additional Information:

Onset date: 02/03 worsened since 02/03. Improved with dose reduction to cease Zoloft. Report 185194 is a seq to report 185598.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185250 **Seq:** 1 **Gender:** M
Reported: 29/04/2003 **Weight:** 125.00
Hospitalisation: **Age:** 24
Onset Date: 21/03/2003 **DOB:** 14/12/1978
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsive threshold lowered	Caused or prolonged inpatient hospitalisation	Convulsive threshold lowered	Diazepam administered. Daily dose of amisulpride reduced to 200mg and finally was cganged to risperidone. Zuclopenthixol and sertraline were also reduced.

Medicine Details:

CLOPIXOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SOLIAN (Suspected) **Reason:**
Tablet
Batch: **Started:** 29/01/2003 **Stopped:**

ZOLOFT (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/04/2003	Radiololgy				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185279 **Seq:** 1
Reported: 28/04/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 50Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizziness, shortness of breath, sweating increased, weakness of limbs	
Bruxism		Teeth grinding, jaw pain, tremor, numbness	
Paraesthesia		Tingling feet/hands, hypertension, tachycardia	
Dyspnoea			
Hyperhidrosis			
Hypertension			
Hypoaesthesia			
Muscular weakness			
Pain in jaw			
Tachycardia			

Medicine Details:

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/04/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient took another dose of Zoloft 50mg the morning of this report, and the symptoms worsened. History: Includes rheumatic fever which affected the patient's heart.

Report Detail

Case Number: 185279 **Seq:** 1
Reported: 28/04/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 50Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases

Tablet Dose Unspecified Oral

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

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 01/04/2003 **Stopped:**

Laboratory Investigations:

Additional Information:

The patient took another dose of Zoloft 50mg the morning of this report, and the symptoms worsened. History: Includes rheumatic fever which affected the patient's heart.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185281 **Seq:** 1 **Gender:** U
Reported: 28/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paralysis Cerebrovascular accident		Left arm paralysed. Stroke and paralysed, described as "if she was having a stroke" (stroke-like symptoms)	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185320 **Seq:** 1 **Gender:** F
Reported: 22/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: 02/04/2003 **DOB:** 18/12/1973
Outcome: Recovered 07/04/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonergic syndrome.	Cyproheptadine 4mg orally TDS

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 12.5 Milligram Daily Oral
Batch: **Started:** 01/04/2003 **Stopped:** 03/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous sertonergic syndrome reaction 16/03/03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185347 **Seq:** 1 **Gender:** U
Reported: 28/04/2003 **Weight:** 89.00
Hospitalisation: **Age:** 34
Onset Date: 01/02/2003 **DOB:** 18/01/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Visit to Doctor	Acute serotonin syndrome with nausea, dizzyness, fever, sweating, photophobia, sever weakness	Ceased Zoloft, Litlium,

Medicine Details:

ZOLOFT (Interaction) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 08/06/2002 **Stopped:** 08/02/2002

LITHIUM CARBONATE (Interaction) **Reason:** Depression
Tablet 1350.0 Milligram Daily Oral
Batch: **Started:** 30/01/2003 **Stopped:** 08/02/2003

GINSENG (Interaction) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:** 08/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/04/2003	Pharmacokinetics				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185364 **Seq:** 1 **Gender:** F
Reported: 28/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 15/02/2003 **DOB:** 15/03/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bursitis	Required Visit to Doctor	Knees - bursitis, nausea and diarrhoea.	
Diarrhoea	Required Visit to Doctor	Knees - bursitis, nausea and diarrhoea.	
Nausea	Required Visit to Doctor	Knees - bursitis, nausea and diarrhoea.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 03/09/2002 **Stopped:** 01/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft resumed. Onset date: 02/03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185498 **Seq:** 1 **Gender:** F
Reported: 05/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough Pneumonitis Dyspnoea		Persistent cough and dyspnoea. Pneumonitis	Zoloft was ceased and symptoms resolved.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/07/2001 **Stopped:** 28/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Developed drug induced pneumonitis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185499 **Seq:** 1 **Gender:** F
Reported: 05/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Dry cough.	
Pneumonitis		Pneumonitis	Ceased Zoloft

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/05/2003	Other data				

Additional Information:

Developed drug induced pneumonitis, persistent crepitations and fine bronchi.
The physician also states that the patient had been receving Zoloft for years. Zoloft was ceased in February 2000.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185524 **Seq:** 1 **Gender:** F
Reported: 14/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 80Y
Onset Date: 13/01/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation	Patient suffered severe anxiety and was found in a semi-conscious state.	Zoloft ceased.
Depressed level of consciousnes	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IMDUR (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
XANAX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
ZOLOFT (Suspected)		**Reason:**	Depression
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Beta blocker(unspecified), Statin (unspecified).
185524 is seq 02 to 184015 seq 01.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185598 **Seq:** 1 **Gender:** F
Reported: 23/04/2003 **Weight:** 103.00
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 01/08/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Required Visit to Doctor	Serotonin syndrome, sweats, tremors, incoordination.	
Hyperhidrosis	Required Visit to Doctor	Serotonin syndrome, sweats, tremors, incoordination.	
Serotonin syndrome	Required Visit to Doctor	Serotonin syndrome, sweats, tremors, incoordination.	
Tremor	Required Visit to Doctor	Serotonin syndrome, sweats, tremors, incoordination.	

Medicine Details:

REDUCTIL (Interaction) **Reason:** Obesity othr than endoc origin
Capsule Dose Unspecified Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Interaction) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 02/03. Dose start and stop date for Zoloft and Reductil - 10/02-04/03 and 09/02-0902. Report 185598 is a seq to 185194.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185723 **Seq:** 1 **Gender:** F
Reported: 10/05/2003 **Weight:** 80.00
Hospitalisation: **Age:** 31
Onset Date: 01/01/2002 **DOB:** 20/04/1970
Outcome: Recovered 01/01/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaphylactic reaction	Caused or prolonged inpatient hospitalisation	severe anaphylaxsis resulting in hospitalisation due to one tablet of Zoloft.	sent to intesive care . IV adrenalin stat monitoring airways

Medicine Details:

ZYBAN SR (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified 2 times Oral
Batch: **Started:** 01/01/2001 **Stopped:** 01/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185768 **Seq:** 1 **Gender:** F
Reported: 02/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 21/04/2003 **DOB:** 02/02/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction	Required Visit to Doctor	Rash on lower half of face and neck (5cm exposed areas?) and photosensitive rash.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 14/04/2003 **Stopped:** 26/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185818 **Seq:** 1 **Gender:** F
Reported: 13/03/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Movement disorder		Patient "Felt hazy" and lightheaded with symptoms worse on movement and withdrawal reaction.	Zoloft recommenced on 18/02/03 at 50mg/day and increased to 100mg/day.

Medicine Details:

STELAZINE (Other drug) **Reason:**
Dose Unspecified Oral
Batch: **Started:** L TERM **Stopped:**

LITHIUM CARBONATE (Other drug) **Reason:**
Tablet Dose Unspecified Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 18/02/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Oroxine and Somac.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185876 **Seq:** 1 **Gender:** F
Reported: 09/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Stress		Convulsions aggravated and stress.	

Medicine Details:

TEGRETOL (Other drug) **Reason:** Convulsions
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 185965 **Seq:** 1 **Gender:** M
Reported: 16/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 09/11/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion	Required Visit to Doctor	Bruising on various parts of body.	
Haematuria	Required Visit to Doctor	Bruising on various parts of body.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 12/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186104 **Seq:** 1
Reported: 22/05/2003
Hospitalisation: Admitted to hospital
Onset Date: 04/05/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 91
DOB: 02/02/1912
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Confusion, difficult behaviour, night terrors, shaking, cold and clammy, palpitations Dx delirium? serotonin syndrome secondary to addition of SSRI to long term TCA tx	Cease antidepressants, add risperidone and oxazepam prn, and IM droperidol for severe agitation with benztropine for epse. Commence mirtazapine once confusion resolved to tx depression. Psych r/v, d/c to
Abnormal behaviour	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRYPTANOL (Interaction) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 11/05/2003

ZOLOFT (Interaction) **Reason:** Depression
Tablet Daily Oral
Batch: **Started:** 04/05/2003 **Stopped:** 11/05/2003

VIOXX (Other drug) **Reason:**
Tablet 12.5 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

BACTRIM (Other drug) **Reason:** Othr diseases of urinary tract
Tablet 400.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:** 11/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186104 **Seq:** 1
Reported: 22/05/2003
Hospitalisation: Admitted to hospital
Onset Date: 04/05/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 91
DOB: 02/02/1912
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug)			**Reason:**		
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
OROXINE (Other drug)			**Reason:**	Myxedema	
Tablet	50.0	Microgram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
LISINOPRIL (Other drug)			**Reason:**	Essential benign hypertension	
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
ALLOPURINOL (Other drug)			**Reason:**	Gout	
Tablet	300.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186104 **Seq:** 1
Reported: 22/05/2003
Hospitalisation: Admitted to hospital
Onset Date: 04/05/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 91
DOB: 02/02/1912
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRYPTANOL (Interaction)			**Reason:**	Depression	
Tablet	75.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	11/05/2003
ZOLOFT (Interaction)			**Reason:**	Depression	
Tablet			Daily		Oral
Batch:	**Started:**	04/05/2003		**Stopped:**	11/05/2003
VIOXX (Other drug)			**Reason:**		
Tablet	12.5	Milligram	1 time		Oral
Batch:	**Started:**			**Stopped:**	
BACTRIM (Other drug)			**Reason:**	Othr diseases of urinary tract	
Tablet	400.0	Milligram	1 time		Oral
Batch:	**Started:**			**Stopped:**	11/05/2003

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 186104 **Seq:** 1
Reported: 22/05/2003
Hospitalisation: Admitted to hospital
Onset Date: 04/05/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 91
DOB: 02/02/1912
Causality: Causality possible

Reaction Detail

Medicine Details:

ASPIRIN (Other drug)			**Reason:**		
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
OROXINE (Other drug)			**Reason:**	Myxedema	
Tablet	50.0	Microgram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
LISINOPRIL (Other drug)			**Reason:**	Essential benign hypertension	
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
ALLOPURINOL (Other drug)			**Reason:**	Gout	
Tablet	300.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186226 **Seq:** 1 **Gender:** M
Reported: 26/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 56
Onset Date: 15/05/2003 **DOB:** 07/10/1946
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Excessive sweating	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 26/02/2003 **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186271 **Seq:** 1
Reported: 28/05/2003
Hospitalisation: Admitted to hospital
Onset Date: 15/09/2000
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 23
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Insomnia, depression aggravated, thinking abnormal, serotonin syndrome, schizophrenia	
Hallucination, auditory	Caused or prolonged inpatient hospitalisation	Insomnia, depression aggravated, thinking abnormal, serotonin syndrome, schizophrenia	
Psychotic disorder	Caused or prolonged inpatient hospitalisation	Insomnia, depression aggravated, thinking abnormal, serotonin syndrome, schizophrenia	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft was started sometime in June 2000, and stopped sometime in september 2000.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186271 **Seq:** 1
Reported: 28/05/2003
Hospitalisation: Admitted to hospital
Onset Date: 15/09/2000
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 23
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Schizophrenia	Caused or prolonged inpatient hospitalisation	Insomnia, depression aggravated, thinking abnormal, serotonin syndrome, schizophrenia	
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Insomnia, depression aggravated, thinking abnormal, serotonin syndrome, schizophrenia	
Thinking abnormal	Caused or prolonged inpatient hospitalisation	Insomnia, depression aggravated, thinking abnormal, serotonin syndrome, schizophrenia	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

Zoloft was started sometime in June 2000, and stopped sometime in september 2000.

Report Detail

Case Number: 186271 **Seq:** 1
Reported: 28/05/2003
Hospitalisation: Admitted to hospital
Onset Date: 15/09/2000
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 23
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitated depression	Caused or prolonged inpatient hospitalisation	Insomnia, depression aggravated, thinking anbnormal, serotonin syndrome, schizophrenia	
Insomnia	Caused or prolonged inpatient hospitalisation	Insomnia, depression aggravated, thinking anbnormal, serotonin syndrome, schizophrenia	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

Zoloft was started sometime in June 2000, and stopped sometime in september 2000.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186452 **Seq:** 1
Reported: 02/06/2003
Hospitalisation: Admitted to hospital
Onset Date: 14/04/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 73Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Tremor	A beta-blocker was introduced.

Medicine Details:

XANAX (Other drug) **Reason:**

Tablet 2.0 Milligram Daily Oral

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

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose was increased to 100mg/daily approximately two to three weeks after Zoloft initiation the tremor worsened and the patient was hospitalised.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186499 **Seq:** 1 **Gender:** F
Reported: 02/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Feeling shaky and dizzy, increased reflux.	Both Zoloft and Tramadol were ceased.
Hyperreflexia		Feeling shaky and dizzy, increased reflux.	Both Zoloft and Tramadol were ceased.
Nervousness		Feeling shaky and dizzy, increased reflux.	Both Zoloft and Tramadol were ceased.

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain

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

ZOLOFT (Interaction) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Serotonin syndrome (unconfirmed)

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186692 **Seq:** 1 **Gender:** M
Reported: 06/06/2003 **Weight:** 67.50
Hospitalisation: **Age:** 48
Onset Date: 29/05/2003 **DOB:** 12/02/1955
Outcome: Recovered 02/06/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension	Required Visit to Doctor	Hypertension BP up 170/100, BP pre treatment 140/80 resolved on discontinuation to 130/90. No hypertension, history of excess Alcohol intake	Zoloft discontinued

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 17/01/2003 **Stopped:** 14/02/2003

VALIUM (Suspected) **Reason:** Depression
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 14/02/2003 **Stopped:** 26/02/2003

EFEXOR (Suspected) **Reason:**
Tablet 75.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186816 **Seq:** 1 **Gender:** M
Reported: 10/06/2003 **Weight:** 95.00
Hospitalisation: **Age:** 61
Onset Date: 30/05/2003 **DOB:** 19/04/1942
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure	Required Visit to Doctor	Patient found he was unable to ejaculate while having sex.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 27/05/2003 **Stopped:** 30/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Minipress, Pravachol, Solprin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186856 **Seq:** 1 **Gender:** F
Reported: 12/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 32Y
Onset Date: 15/07/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Spontaneous abortion	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Initiated on Zoloft 50mg/daily in approximately 12/2000. The physician states that the Zoloft dose was increased fairly quickly to 100mg/daily. The patient experienced two spontaneous abortions in July/01 and April/03. History: Normal pregnancy prior to Zoloft initiation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 186967 **Seq:** 1 **Gender:** F
Reported: 16/06/2003 **Weight:** 91.00
Hospitalisation: **Age:** 60
Onset Date: 05/06/2003 **DOB:** 23/07/1942
Outcome: Recovered 10/06/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness Trismus		Trismus and neck shiffness for 5 days. Trismus and neck shiffness for 5 days.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 03/06/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Took Zoloft 25mg for 2/7 after increased to 50 symptoms occurred at increased dosage. Other drugs: Karvea, Panamax, premarin, Venolin and Seretide.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187016 **Seq:** 1 **Gender:** F
Reported: 18/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 11/06/2003 **DOB:** 06/03/1953
Outcome: Recovered 13/06/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain		Unresponsive, increased blood pressure, severe headache, urinary retention requiring catheterisation, unable to swallow, chest pain, confusion/agitation.	
Dysphagia		Unresponsive, increased blood pressure, severe headache, urinary retention requiring catheterisation, unable to swallow, chest pain, confusion/agitation.	
Hypertension		Unresponsive, increased blood pressure, severe headache, urinary retention requiring catheterisation, unable to swallow, chest pain, confusion/agitation.	

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**
Tablet 100.0 Milligram 1 time Oral
Batch: **Started:** 11/06/2003 **Stopped:**

ZOLOFT (Interaction) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 12/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Avapro, Voltaren, Panadol and Flucloxacillin.

Report Detail

Case Number: 187016 **Seq:** 1 **Gender:** F
Reported: 18/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 50
Onset Date: 11/06/2003 **DOB:** 06/03/1953
Outcome: Recovered 13/06/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Unresponsive, increased blood pressure, severe headache, urinary retention requiring catheterisation, unable to swallow, chest pain, confusion/agitation.	
Urinary retention		Unresponsive, increased blood pressure, severe headache, urinary retention requiring catheterisation, unable to swallow, chest pain, confusion/agitation.	

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**
Tablet 100.0 Milligram 1 time Oral
Batch: **Started:** 11/06/2003 **Stopped:**

ZOLOFT (Interaction) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 12/06/2003

Laboratory Investigations:

Additional Information:
Patient also taking Avapro, Voltaren, Panadol and Flucloxacillin.

Report Detail

Case Number: 187051 **Seq:** 1 **Gender:** U
Reported: 19/06/2003 **Weight:** 64.00
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 20/05/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Severe nausea and vomiting	
Vomiting	Required Visit to Doctor	Severe nausea and vomiting	

Medicine Details:

POSTINOR-2 (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187060 **Seq:** 1 **Gender:** F
Reported: 19/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 40
Onset Date: 01/06/2003 **DOB:** 01/06/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Non-accidental overdose, suicide atempt.	
Suicide attempt		Non-accidental overdose, suicide atempt.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 12/03/2003 **Stopped:** contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took an overdose of 25 x 50mg Zoloft tablets.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187101 **Seq:** 1 **Gender:** F
Reported: 26/05/2003 **Weight:** 90.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered without treatment **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Aggression		Patient suddenly "snapped" and became aggressive and threatened her husband with a knife. No previous history of violence or aggression.	No treatment sought. Patient went to bed after episode (duration 30 minutes) and has been well since.

Medicine Details:

TAMOXIFEN CITRATE (Suspected) **Reason:** Malignant neoplasm of breast
Batch: **Started:** **Stopped:**

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/02/2003 **Stopped:**

MERSYNDOL (Suspected) **Reason:** Pain
Tablet 6.0 Dose Unspecified Daily Oral
Batch: **Started:** 01/02/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had consumed approximately 5-6 standard drinks in the hours leading up to the episode.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187136 **Seq:** 1 **Gender:** F
Reported: 20/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 17
Onset Date: 14/06/2003 **DOB:** 28/02/1986
Outcome: Recovered 16/06/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Hallucinations	
Hallucination	Required Visit to Doctor	Hallucinations	

Medicine Details:

STILNOX (Suspected) **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 13/06/2003 **Stopped:** 15/06/2003

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 13/06/2003 **Stopped:** 16/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187539 **Seq:** 1 **Gender:** F
Reported: 23/06/2003 **Weight:** 58.00
Hospitalisation: **Age:** 69
Onset Date: 05/10/2000 **DOB:** 03/09/1931
Outcome: Recovered 13/10/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dementia	Caused or prolonged inpatient hospitalisation	Dementia, coordination impaired and	
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia, weight decreased, low back pain, abdominal distension	Ceased Zoloft.
Urine osmolarity decreased	Caused or prolonged inpatient hospitalisation	Urine osmolaity decreased, blood osmolarity decreased	

Medicine Details:

ATENOLOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CHLOROTHIAZIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/06/2003	Potassium	(3.4-5.2)	05/10/2000	2.9	
23/06/2003	Potassium	(3.4-5.2)	10/05/2000	4.3	
23/06/2003	Potassium	(3.4-5.2)	11/10/2000	3.8	
23/06/2003	Serum osmolality				
23/06/2003	Sodium	138-145	05/10/2000	121	
23/06/2003	Sodium	138-145	10/05/2000	132	
23/06/2003	Sodium	138-145	11/10/2000	134	

Additional Information:

History includes hypertension, osteoarthritis (OA) and reflux oesophagitis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187539 **Seq:** 1 **Gender:** F
Reported: 23/06/2003 **Weight:** 58.00
Hospitalisation: **Age:** 69
Onset Date: 05/10/2000 **DOB:** 03/09/1931
Outcome: Recovered 13/10/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual acuity reduced	Caused or prolonged inpatient hospitalisation	Vision decreased, hypoacusis, throat irritation, blood pressure decreased,	
Abdominal distension	Caused or prolonged inpatient hospitalisation		
Back pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATENOLOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CHLOROTHIAZIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/06/2003	Urine osmolality				

Additional Information:

History includes hypertension, osteoarthritis (OA) and reflux oesophagitis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187539 **Seq:** 1 **Gender:** F
Reported: 23/06/2003 **Weight:** 58.00
Hospitalisation: **Age:** 69
Onset Date: 05/10/2000 **DOB:** 03/09/1931
Outcome: Recovered 13/10/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood osmolarity decreased	Caused or prolonged inpatient hospitalisation		
Blood pressure decreased	Caused or prolonged inpatient hospitalisation		
Coordination abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATENOLOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CHLOROTHIAZIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/10/2000

Laboratory Investigations:

Additional Information:
History includes hypertension, osteoarthritis (OA) and reflux oesophagitis.

Report Detail

Case Number: 187539 **Seq:** 1 **Gender:** F
Reported: 23/06/2003 **Weight:** 58.00
Hospitalisation: **Age:** 69
Onset Date: 05/10/2000 **DOB:** 03/09/1931
Outcome: Recovered 13/10/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoacusis	Caused or prolonged inpatient hospitalisation		
Hypokalaemia	Caused or prolonged inpatient hospitalisation		
Throat irritation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATENOLOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CHLOROTHIAZIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/10/2000

Laboratory Investigations:

Additional Information:
History includes hypertension, osteoarthritis (OA) and reflux oesophagitis.

Report Detail

Case Number: 187539 **Seq:** 1 **Gender:** F
Reported: 23/06/2003 **Weight:** 58.00
Hospitalisation: **Age:** 69
Onset Date: 05/10/2000 **DOB:** 03/09/1931
Outcome: Recovered 13/10/2000 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATENOLOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CHLOROTHIAZIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/10/2000

Laboratory Investigations:

Additional Information:

History includes hypertension, osteoarthritis (OA) and reflux oesophagitis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187695 **Seq:** 1 **Gender:** F
Reported: 25/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 90
Onset Date: 06/11/2002 **DOB:** 04/05/1912
Outcome: Recovered 07/11/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		30 Minutes after taking 1/2 a Zoloft tablet patient experienced nausea and "thought running around my head".	Mazolon 10mg IM, Temazepam 10mg nocte, stay overnight for observation and ceased Zoloft.
Nausea		30 Minutes after taking 1/2 a Zoloft tablet patient experienced nausea and "thought running around my head".	
Thinking abnormal		30 Minutes after taking 1/2 a Zoloft tablet patient experienced nausea and "thought running around my head".	
Vomiting		30 Minutes after taking 1/2 a Zoloft tablet patient experienced nausea and "thought running around my head".	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 0.5 Dose Unspecified 1 time Oral
Batch: **Started:** 06/11/2002 **Stopped:** 06/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Panamax, Solprin and Mogadon.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187768 **Seq:** 1 **Gender:** U
Reported: 24/06/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 16/06/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia		Menorrhagia	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 16/06/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Flagyl and Trifeme.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187824 **Seq:** 1 **Gender:** F
Reported: 28/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 16/01/2003 **DOB:** 18/08/1971
Outcome: Recovered 25/01/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation	Increased agitation, obsessive thoughts, violent thoughts and suicidal ideation.	Ceased Zoloft
Obsessive thoughts			
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/01/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar reaction with father (agitated) (past): While receiving Zoloft.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187824 **Seq:** 1 **Gender:** F
Reported: 28/04/2003 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 16/01/2003 **DOB:** 18/08/1971
Outcome: Recovered 25/01/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Violent ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/01/2003 **Stopped:**

Laboratory Investigations:

Additional Information:

Similar reaction with father (agitated) (past): While receiving Zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187832 **Seq:** 1
Reported: 03/07/2003
Hospitalisation:
Onset Date: 29/04/2003
Outcome: Recovered with sequelae

Gender: M
Weight: 0.00
Age: 52
DOB: 24/01/1951
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation	Lithium toxicity (level 2.9mmol/L)requiring hospitalisation. Patient presented with a one week history of increasing confusion, wandering, inappropriate speech, loss of appetite. Past history of alcoholism, peripheral neuropathy, NIDDM, bipolar disorder	Lithium was withheld. Level fell to normal within 3 days but psychotic symptoms persisted for over a week, even in the presence of low lithium levels. Possible interaction with Vioxx considered
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Interaction)			**Reason:**	
Tablet	250.0 Milligram	4 times		Oral
Batch:	**Started:** 01/01/2000		**Stopped:**	29/04/2003
TRAMAL (Interaction)			**Reason:**	
Capsule	50.0 Milligram	3 times		Oral
Batch:	**Started:** 13/03/2003		**Stopped:**	03/05/2003
VIOXX (Interaction)			**Reason:**	
Tablet	12.5 Milligram	1 time		Oral
Batch:	**Started:** 01/04/2003		**Stopped:**	
ZOLOFT (Interaction)			**Reason:**	
Tablet	100.0 Milligram	1 time		Oral
Batch:	**Started:** 01/01/2001		**Stopped:**	29/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/07/2003	Serum drug level				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187832 **Seq:** 1
Reported: 03/07/2003
Hospitalisation:
Onset Date: 29/04/2003
Outcome: Recovered with sequelae

Gender: M
Weight: 0.00
Age: 52
DOB: 24/01/1951
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Decreased appetite	Caused or prolonged inpatient hospitalisation		
Restlessness	Caused or prolonged inpatient hospitalisation		
Speech disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Interaction) **Reason:**
Tablet 250.0 Milligram 4 times Oral
Batch: **Started:** 01/01/2000 **Stopped:** 29/04/2003

TRAMAL (Interaction) **Reason:**
Capsule 50.0 Milligram 3 times Oral
Batch: **Started:** 13/03/2003 **Stopped:** 03/05/2003

VIOXX (Interaction) **Reason:**
Tablet 12.5 Milligram 1 time Oral
Batch: **Started:** 01/04/2003 **Stopped:**

ZOLOFT (Interaction) **Reason:**
Tablet 100.0 Milligram 1 time Oral
Batch: **Started:** 01/01/2001 **Stopped:** 29/04/2003

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187850 **Seq:** 1
Reported: 30/06/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 30
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Severe	Severe vomitting	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 187910 **Seq:** 1
Reported: 30/06/2003
Hospitalisation: Admitted to hospital
Onset Date: 01/06/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 75Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia	Caused or prolonged inpatient hospitalisation	Hypokalaemia	Suspected drugs ceased
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 02/06/2003

COVERSYL PLUS (Suspected) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 25/03/2003 **Stopped:** 02/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/06/2003	Potassium		28/05/2003	4	
30/06/2003	Potassium		01/06/2003	3.1	
30/06/2003	Potassium		02/06/2003	3	
30/06/2003	Sodium		28/05/2003	124	
30/06/2003	Sodium		01/06/2003	115	
30/06/2003	Sodium		02/06/2003	121	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 188106 **Seq:** 1
Reported: 02/07/2003
Hospitalisation: Admitted to hospital
Onset Date: 09/06/2003
Outcome: Not yet recovered

Gender: F
Weight: 80.00
Age: 15
DOB: 10/05/1988
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism Deep vein thrombosis		Pulmonary embolus and DVT of calf - right	Given Heparin infusion and Warfarinise.

Medicine Details:

Yasmin (Suspected) **Reason:** Contraception

Tablet 1.0 Dose Unspecified Daily Oral

Batch: **Started:** **Stopped:** 09/06/2003

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 09/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/07/2003	Other data				VIQ scan intermediate probability of PE.

Additional Information:

Dose start dates: 03/2003 and 03/2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 188155 **Seq:** 1 **Gender:** M
Reported: 03/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 67
Onset Date: 24/06/2003 **DOB:** 19/05/1936
Outcome: Recovered 26/06/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bradycardia		Bradycardia 38/min.	Drugs ceased. Monitor in coronary care unit.

Medicine Details:

BETALOC (Suspected) **Reason:** Chron isch heart dis no hyper
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 24/06/2003

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 24/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was already in hospital.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 188483 **Seq:** 1 **Gender:** F
Reported: 14/07/2003 **Weight:** 56.00
Hospitalisation: **Age:** 27
Onset Date: 09/07/2003 **DOB:** 04/05/1976
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Visit to Doctor	Severe Agitation , Panic attack and	
Insomnia	Required Visit to Doctor	Severe Agitation , Panic attack and	
Panic attack	Required Visit to Doctor	Severe Agitation , Panic attack and	

Medicine Details:

MICROGYNON (Other drug) **Reason:** Contraception
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 09/07/2003 **Stopped:** 10/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 188640 **Seq:** 1 **Gender:** F
Reported: 12/05/2003 **Weight:** 0.00
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Nausea		Diarrhoea, nausea Diarrhoea, nausea	Sertraline ceased.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Batch: **Started:** 25/04/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had pre-existing tacycardia.
Family history of cardiac problems, concurrent illnesses include: social isolation, behavioural changes, inappropriate quilt.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 188897 **Seq:** 1 **Gender:** F
Reported: 28/07/2003 **Weight:** 0.00
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 27/07/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swelling face	Treated in outpatient department only	Swelling of face and lip	Hydrocortisone and Phenergan
Lip swelling	Treated in outpatient department only		

Medicine Details:

SODIUM CHLORIDE (Suspected) **Reason:** Pain
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 09/05/2003 **Stopped:** 10/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189070 **Seq:** 1
Reported: 31/07/2003
Hospitalisation:
Onset Date: 31/05/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 20
DOB: 18/10/1982
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Failure to Ejaculate	Clozaril was decreased form 500mg to 450mg daily.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 29/05/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189103 **Seq:** 1
Reported: 30/07/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 45.00
Age: 55
DOB: 15/09/1947
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise	Life	Feeling unwell	
Weight decreased	Life	Has lost 10kgs over the last 8 to 10	
Pruritus	Life	Itchy	
Skin discolouration	Life	Skin discolouration	
Yellow skin	Life	Yellow skin	Patient started feeling better after one week. patient required a visit to

Medicine Details:

TEMAZEPAM (Other drug) **Reason:** Specific disorders of sleep
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SOTALOL HYDROCHLORIDE (Other drug) **Reason:** Otr&nos disord of heart rhythm
Tablet 160.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/07/2003	Liver biopsy				

Additional Information:

Onset date: 06/2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189113 **Seq:** 1 **Gender:** F
Reported: 05/08/2003 **Weight:** 54.00
Hospitalisation: **Age:** 17
Onset Date: 21/07/2003 **DOB:** 09/01/1986
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Deafness Blindness		Sudden hearing loss and visual loss,	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 10/04/2003 **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 189275 **Seq:** 1 **Gender:** F
Reported: 07/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 11
Onset Date: 31/01/2003 **DOB:** 30/05/1991
Outcome: Recovered 04/03/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Syndrome of inappropriate ADH secretion and hypovalaemia.	
Hypovolaemia		Syndrome of inappropriate ADH secretion and hypovalaemia.	Given IV fluids and Potassium supplements.

Medicine Details:

AVAPRO HCT 300/12.5 (Suspected) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/08/2003	Other data				

Additional Information:

Other drugs: Celebrex, Carvedilol, Somac, Amiodarone and Xalaten eye drops.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189435 **Seq:** 1
Reported: 13/08/2003
Hospitalisation: Admitted to hospital
Onset Date: 11/06/2003
Outcome: Unknown

Gender: F
Weight:
Age: 38
DOB: 21/08/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Limb reduction defect Drug exposure during pregnancy		Foetus - absence of left arm with only a very short humeral segment and no distal bones or fingers.	Termination

Medicine Details:

ZOLOFT (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

G3P2 at 18/40 admiited for termination

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189511 **Seq:** 1 **Gender:** F
Reported: 13/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 15/09/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice Hepatitis cholestatic Weight decreased		Jaundice, weight loss and cholestatic	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 30/08/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/08/2003	ALT = SGPT	< 51	04/08/2003	453	
13/08/2003	ALT = SGPT	< 51	23/06/2003	446	
13/08/2003	AST = SGOT	< 41	04/08/2003	799 U / L	
13/08/2003	Albumin	35-50	04/08/2003	39 g / L	
13/08/2003	Bilirubin	<25	04/08/2003	113 umol /L	
13/08/2003	Bilirubin	<25	23/06/2003	270	
13/08/2003	GGT = SGGT =	< 51	04/08/2003	883	

Additional Information:

Patient told to stop Zoloft after had liver biopsy. 3 days later felt improved. Is now back at work. Weight loss has ceased, and jaundice is fading. ERCP was normal on 07/07/03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189511 **Seq:** 1 **Gender:** F
Reported: 13/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 15/09/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)			**Reason:** Depression	
Tablet	50.0	Milligram	Daily	Oral
Batch:	**Started:** 30/08/2003		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/08/2003	GGT = SGGT =	< 51	23/06/2003	849	
13/08/2003	Liver biopsy		23/06/2003	270 umol / L	
13/08/2003	Protein	60-82	04/08/2003	65 g / L	

Additional Information:

Patient told to stop Zoloft after had liver biopsy. 3 days later felt improved. Is now back at work. Weight loss has ceased, and jaundice is fading. ERCP was normal on 07/07/03.

Report Detail

Case Number: 189706 **Seq:** 1
Reported: 20/08/2003
Hospitalisation: Admitted to hospital
Onset Date: 24/07/2003
Outcome: Unknown

Gender: F
Weight: 50.00
Age: 16
DOB: 29/08/1986
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Continuous shaking.	
Dyspnoea		Couldn't breath.	
Eye rolling		Eyes went black and couldn't open them.	
Amnesia		Memory loss.	
Swollen tongue		Tongue was swollen.	

Medicine Details:

ZOLOFT (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

IMIGRAN (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

MAGNESIUM NOS (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 17/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to wheat - migrains.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189719 **Seq:** 1 **Gender:** F
Reported: 20/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 79
Onset Date: 02/05/2003 **DOB:** 11/03/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		Acute mycardial infarction	
Cataract		Cataracts	
Dizziness		Dizziness	
Duodenal ulcer		Duodenal ulcer	
Hyponatraemia		Hyponatraemia	
Insomnia		Insomnia	
Inappropriate antidiuretic hormon		Suspected SIADH.	

Medicine Details:

PNEUMOCOCCAL VACCINE (Suspected) **Reason:** Prophylactic inoculation and vaccination
Injection 1.0 Dose Unspecified 1 time
Batch: **Started:** 17/09/2001 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 30/11/2000 **Stopped:** 02/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Karvea HCT, Warfarin, Amiodarone, Temazepam, Simvastatin and Influenza virus vaccine. History: Arthritis 01/01/1998 - present, hyperlipedaemia 01/01/1990 - present, hypertension 01/01/1998 - present.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189789 **Seq:** 1 **Gender:** F
Reported: 22/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 92
Onset Date: 10/08/2003 **DOB:** 10/06/1911
Outcome: Recovered 11/08/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation	Required Visit to Doctor	Patient awoke disoriented, became confused and hallucinating during the day.	Stopped Tramal and on 13/8 changed to Endone.
Confusional state	Required Visit to Doctor		
Hallucination	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Interaction) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRAMAL (Interaction) **Reason:**
Capsule 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other medications taken: Imdur, Multivitamin, Metoprolol, Lipitor, Calciparine.
There were no known allergies before admission.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189796 **Seq:** 1
Reported: 25/08/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 25Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancreatitis acute	Caused or prolonged inpatient hospitalisation	Acute pancreatitis.	
Blood cholesterol increased		High cholesterol.	
Weight increased		Weight gain.	

Medicine Details:

ZYPREXA (Suspected) **Reason:** Obsessive compulsive neurosis

Tablet 10.0 Milligram Daily Oral

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

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recommended sertraline hydrochloride at 25mg/day. The reporter believes the events of weight gain and high cholesterol could possibly be related to olanzaphine and does not know if the pancreatitis was related to the olanzaphine treatment. Date of onset July 2003. Therapy with zyprexa started in April 2003

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189818 **Seq:** 1 **Gender:** F
Reported: 25/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 38Y
Onset Date: 15/07/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Body temperature increased		Neuroleptic malignant syndrome, body temperature increased, muscle stiffness, joint stiffness, leukocytosis, tachypnoea, sweating	Treatment in hospital included intravenous fluids, intravenous antibiotics and further investigations
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Joint stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) **Reason:**
Oral application 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** contin

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

About 12 months after taking Olanzapine consistently the patient has experienced Neuroleptic Malignant Syndrome or Serotonergic Syndrome.
Patient was discharged and is under the care of a cardiologist for Myocarditis. The patient is continuing on Olanzapine treatment.

Report Detail

Case Number: 189818 **Seq:** 1 **Gender:** F
Reported: 25/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 38Y
Onset Date: 15/07/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Tachypnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected) **Reason:**

Oral application	10.0	Milligram	Daily	Oral

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

ZOLOFT (Suspected) **Reason:** Depression

Tablet	200.0	Milligram	Daily	Oral

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

Laboratory Investigations:

Additional Information:

About 12 months after taking Olanzapine consistently the patient has experienced Neuroleptic Malignant Syndrome or Serotonergic Syndrome.
Patient was discharged and is under the care of a cardiologist for Myocarditis. The patient is continuing on Olanzapine treatment.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189849 **Seq:** 1
Reported: 25/08/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 19
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonin Syndrome.	Ceased St John's Wort.

Medicine Details:

HYPERICUM-ST JOHN'S WORT (Interaction) **Reason:**

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

ZOLOFT (Interaction) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Serotonin syndrome type symptoms. The physician sent the patient to the hospital. The hospital physician said that the patient did not have serotonin syndrome.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189850 **Seq:** 1 **Gender:** M
Reported: 26/08/2003 **Weight:** 70.00
Hospitalisation: **Age:** 67
Onset Date: 09/03/2003 **DOB:** 10/10/1935
Outcome: Recovered 25/03/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypomania	Required Visit to Doctor	Hypomania, Gambling Problem.	Zoloft ceased, Cipramil low dose started.
Pathological gambling	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/11/2002 **Stopped:** 04/03/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Cabergoline, Parlodel, Sinemet 100/25, Viagra and Losec.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189854 **Seq:** 1 **Gender:** F
Reported: 26/08/2003 **Weight:** 78.00
Hospitalisation: **Age:** 79
Onset Date: 25/07/2003 **DOB:** 28/10/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Depression, hallucinations, loss of appetite,	Started on Sertraline 25mg in the morning.
Weight decreased	Required Visit to Doctor	Depression, hallucinations, loss of appetite,	Started on Sertraline 25mg in the morning.
Insomnia	Required Visit to Doctor	Poor sleep with vivid dreams which were quite scary.	
Hallucination	Required Visit to Doctor	She also noted when she was lying in bed at night once the light was off, she would have hallucinations of people standing around her and bending over her.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/08/2003	Other data				

Additional Information:

Patient also administered: Aspirin 150mg daily, Caltrate 1 mane, Glucosamine 120mg daily, Vitamin C 500mg daily, Ferro Gradumet 1 daily, Natural fish oil 1000 1 daily, Chelated zinc 220mg daily, L-lyosine complex 1 daily, Temazepan 10mg nocte and Silica compound 50mg daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189854 **Seq:** 1 **Gender:** F
Reported: 26/08/2003 **Weight:** 78.00
Hospitalisation: **Age:** 79
Onset Date: 25/07/2003 **DOB:** 28/10/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Required Visit to Doctor	She complained of headaches unrelieved by analgesics and the sensation of things spinning around.	
Decreased appetite	Required Visit to Doctor	She descrobed her appetite as being ppor and felt she had lost weight as her clothes were a little loose. Certain foods would nauseate her as well. She would cook something she fancied, but by the time she dished it up, would then take a few mouthfuls and not be able to continue to eat.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Patient also administered: Aspirin 150mg daily, Caltrate 1 mane, Glucosamine 120mg daily, Vitamin C 500mg daily, Ferro Gradumet 1 daily, Natural fish oil 1000 1 daily, Chelated zinc 220mg daily, L-lyosine complex 1 daily, Temazepan 10mg nocte and Silica compound 50mg daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189854 **Seq:** 1 **Gender:** F
Reported: 26/08/2003 **Weight:** 78.00
Hospitalisation: **Age:** 79
Onset Date: 25/07/2003 **DOB:** 28/10/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Irritability	Required Visit to Doctor	She found having people around was getting on her nerves and she could just not put up with them. This even occurred with close family members.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Patient also administered: Aspirin 150mg daily, Caltrate 1 mane, Glucosamine 120mg daily, Vitamin C 500mg daily, Ferro Gradumet 1 daily, Natural fish oil 1000 1 daily, Chelated zinc 220mg daily, L-lyosine complex 1 daily, Temazepan 10mg nocte and Silica compound 50mg daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189881 **Seq:** 1
Reported: 27/08/2003
Hospitalisation:
Onset Date: 12/05/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 21
DOB: 08/04/1982
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Headache Sleep disorder Suicidal ideation Tearfulness		Diarrhoea, suicidal ideation, sleep disorder nos, asthenia, headache, tearfulness.	Temazepam.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 12/05/2003 **Stopped:** 27/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was started on 50mg daily, experienced diarrhoea , Zoloft was decreased to 25mg and symptoms settled, then zoloft was increased to 50mg, the 100mg felt suicidal.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189884 **Seq:** 1 **Gender:** F
Reported: 27/08/2003 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 23/06/1978
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Drug withdrawal syndrome		Seizures Seizures returned when the patient was withdrawing from Zoloft.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/08/2003	Other data				

Additional Information:

History: Sleep walking, seizures-petit mal. The patient's zoloft dose was reduced to 25mg for a few days each week in early 2003 and the episodes returned. The patient 's zoloft dose was again increased to 50mg daily in June 2003 and the episodes stopped. Patient also taking contraceptive pill.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 189953 **Seq:** 1
Reported: 29/08/2003
Hospitalisation: Admitted to hospital
Onset Date: 01/03/2001
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 51
DOB: 26/02/1950
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation	Mania Experienced a hypermanic episode	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 28/11/2000 **Stopped:** 06/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of substance abuse (present)

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190305 **Seq:** 1 **Gender:** F
Reported: 08/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon Hyponatraemia	Caused or prolonged inpatient hospitalisation	Sodium decreased, siadh.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other sustected drug duretic (unspecified).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190309 **Seq:** 1 **Gender:** F
Reported: 08/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 75Y
Onset Date: 27/02/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state Headache Malaise Tardive dyskinesia Condition aggravated		Increased tardive dyskinesia, confusion and agitation, headache and feeling unwell	Olanzapine 5mg nocte and Lorazepam prn. Therapy ceased

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**		
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	27/02/2003
AMISULPRIDE (Suspected)			**Reason:**		
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	27/02/2003
COGENTIN (Suspected)			**Reason:**		
Tablet	2.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	27/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of tardive dyskinesia (chewing, biting) resulted from Stelazine 30years ago. Patient prone to agitation and depression. Other drugs used: Lorazepam, Olanzapine, Mirtazapine, Aspirin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190464 **Seq:** 1 **Gender:** F
Reported: 15/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 24/07/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination		Hallucinations	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 05/07/2003 **Stopped:** 26/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: ostelin, caltrate, nitrodur, metoprolol, nilstat, coloxyl supp.
Dexamethosone caused hallucinations

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190518 **Seq:** 1 **Gender:** F
Reported: 15/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 72
Onset Date: 14/04/2003 **DOB:** 01/05/1930
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation	Tremor Bilateral arm/hand tremor, which was initially mild, then increased in severity involving arms, neck and head.	Zoloft was discontinued, patient was initiated on atenol (unspecified) 50mg daily

Medicine Details:

ALPRAZOLAM (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** 09/04/2003 **Stopped:** 05/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190536 **Seq:** 1 **Gender:** F
Reported: 16/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 21/09/1947
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cholelithiasis Anorexia Hepatitis cholestatic Hypokalaemia Jaundice Lethargy		Cholelithiasis, hypokalaemia, cholestatic hepatitis, jaundice.	Ceased Zoloft

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 30/08/2002 **Stopped:** 12/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/09/2003	ALT = SGPT	<51	23/06/2003	446	
16/09/2003	ALT = SGPT	<51	10/07/2003	251	
16/09/2003	ALT = SGPT	<51	04/08/2003	453	
16/09/2003	ALT = SGPT	<51	09/10/2003	77	
16/09/2003	AST = SGOT	<41 U/L	23/06/2003	948	
16/09/2003	AST = SGOT	<41 U/L	09/10/2003	78	
16/09/2003	AST = SGOT	<41 U/L	10/07/2003	462	

Additional Information:

Patient also administered: Sotalol, Temazepam.
Reaction occurred June 2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190536 **Seq:** 1 **Gender:** F
Reported: 16/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 21/09/1947
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 30/08/2002 **Stopped:** 12/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/09/2003	AST = SGOT	<41 U/L	04/08/2003	799	
16/09/2003	Albumin	30-50	23/06/2003	37	
16/09/2003	Bilirubin	<25 umol/L	10/07/2003	226	
16/09/2003	Bilirubin	<25 umol/L	09/10/2003	13	
16/09/2003	Bilirubin	<25 umol/L	04/08/2003	113	
16/09/2003	Chloride	95-110	23/06/2003	98	
16/09/2003	Creatinine	0.05-0.1	23/06/2003	0.11	

Additional Information:

Patient also administered: Sotalol, Temazepam.
Reaction occurred June 2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190536 **Seq:** 1
Reported: 16/09/2003
Hospitalisation:
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 55
DOB: 21/09/1947
Causality: Causality probable

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 30/08/2002 **Stopped:** 12/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/09/2003	GGT = SGGT = [illegible]	<51	23/06/2003	849	
16/09/2003	GGT = SGGT = [illegible]	<51	09/10/2003	264	
16/09/2003	GGT = SGGT = [illegible]	<51	10/07/2003	824	
16/09/2003	GGT = SGGT = [illegible]	<51	04/08/2003	883	
16/09/2003	SAP = ALP	30 - 120 U/L	23/06/2003	490	
16/09/2003	SAP = ALP	30 - 120 U/L	10/07/2003	577	
16/09/2003	SAP = ALP	30 - 120 U/L	04/08/2003	715	

Additional Information:

Patient also administered: Sotalol, Temazepam.
Reaction occurred June 2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190536 **Seq:** 1 **Gender:** F
Reported: 16/09/2003 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 21/09/1947
Outcome: Recovered **Causality:** Causality probable

Reaction Detai

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 30/08/2002 **Stopped:** 12/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/09/2003	SAP = ALP	30 - 120 U/L	09/10/2003	207	
16/09/2003	Urea	2.5-8.5	23/06/2003	4.9	
16/09/2003	bicarbonate	20-32	23/06/2003	30	

Additional Information:

Patient also administered: Sotalol, Temazepam.
Reaction occurred June 2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190600 **Seq:** 1
Reported: 27/08/2003
Hospitalisation: Admitted to hospital
Onset Date: 30/05/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 21
DOB: 14/04/1982
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Life	Diarrhoea nos, suicidal disorder, impaired driving ability, weight loss, obsessive reaction, anxiety, dry mouth, nausea, dydpepsia, mydriasis	Zoloft was ceased 27/06/03.
Amnesia	Life	Unable to count backwards.	
Anxiety	Life		
Disturbance in attention	Life		
Dry mouth	Life		
Dyspepsia	Life		
Nausea	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 12/05/2003 **Stopped:** 27/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient dose of Zoloft was inceased to 100mg, on the 30/05/03 and experienced symptoms, on 19/06/03 drug was increased to 150mg daily and experienced more symptoms, Zoloft was ceased.
Patient was also taking temazepam.
History :Gilbert's Syndrome.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190600 **Seq:** 1
Reported: 27/08/2003
Hospitalisation: Admitted to hospital
Onset Date: 30/05/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 21
DOB: 14/04/1982
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder	Life		
Reading disorder	Life		
Suicidal ideation	Life		
Weight decreased	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 12/05/2003 **Stopped:** 27/06/2003

Laboratory Investigations:

Additional Information:

Patient dose of Zoloft was inceased to 100mg, on the 30/05/03 and experienced symptoms, on 19/06/03 drug was increased to 150mg daily and experienced more symptoms, Zoloft was ceased.
Patient was also taking temazepam.
History :Gilbert's Syndrome.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190601 **Seq:** 1
Reported: 27/08/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 21
DOB: 09/04/1982
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia	Life	Disoriented and confused, disturbance of concentration, could not do serial 7's slow with serial 3's.	
Suicidal ideation	Life	Suicidal ideation, Dizziness, Myalgia, Aggression, withdrawal reaction, thyroid stimulating hormone decreased.	Ceased Zoloft. Trial of Efexor.
Aggression	Life		
Blood thyroid stimulating hormon	Life		
Confusional state	Life		
Dizziness	Life		
Drug withdrawal syndrome	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 12/05/2003 **Stopped:** 27/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Gilbert's syndrome.
Confusional state or a discontinuation syndrome.
Thyroid stimulating horme on 15 July 2003 of 0.3IU with refereence range 0.5-5.00 (units unspecified).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190601 **Seq:** 1
Reported: 27/08/2003
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 21
DOB: 09/04/1982
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 12/05/2003 **Stopped:** 27/07/2003

Laboratory Investigations:

Additional Information:

History: Gilbert's syndrome.
Confusional state or a discontinuation syndrome.
Thyroid stimulating horme on 15 July 2003 of 0.3IU with refereence range 0.5-5.00 (units unspecified).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 190620 **Seq:** 1
Reported: 18/09/2003
Hospitalisation:
Onset Date: 10/09/2003
Outcome: Not yet recovered

Gender: M
Weight: 70.00
Age: 23
DOB: 20/10/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia	Required Visit to Doctor	Gynaecomastia of the right nipple and another breast lump found in the left breast upper, medial quad.	
Breast mass	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:** Unspecified neurosis
5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/09/2003	Other data				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191101 **Seq:** 1
Reported: 07/10/2003
Hospitalisation: Admitted to hospital
Onset Date: 26/07/2003
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness	Caused or prolonged inpatient hospitalisation	Patient collapsed with LOC,	Ceased Zoloft and Natrilix.
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

NATRILIX (Suspected) **Reason:**
1.5 Milligram Daily
Batch: **Started:** **Stopped:** 26/07/2003

ZOLOFT (Suspected) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** **Stopped:** 28/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2003	Other data				

Additional Information:

Patient also administered: Xalatan, Somac, Actonel, Naprosyn, Avapro.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191124 **Seq:** 1 **Gender:** F
Reported: 07/10/2003 **Weight:** 50.00
Hospitalisation: **Age:** 99U
Onset Date: 25/09/2003 **DOB:**
Outcome: Recovered 27/09/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Required Visit to Doctor	Acute onset nausea, vomiting, loss of balance, rigidity, sweating and eyes rolling back in head, tachycardia.	
Balance disorder	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		
Muscle rigidity	Required Visit to Doctor		
Nystagmus	Required Visit to Doctor		

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 26/02/2003 **Stopped:** 25/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Settled with reduction of dose to 50mg second daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191124 **Seq:** 1 **Gender:** F
Reported: 07/10/2003 **Weight:** 50.00
Hospitalisation: **Age:** 99U
Onset Date: 25/09/2003 **DOB:**
Outcome: Recovered 27/09/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Required Visit to Doctor		

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 26/02/2003 **Stopped:** 25/09/2003

Laboratory Investigations:

Additional Information:

Settled with reduction of dose to 50mg second daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191147 **Seq:** 1 **Gender:** M
Reported: 07/10/2003 **Weight:** 0.00
Hospitalisation: Treated in outpatient department only. **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Extreme nausea	
Oedema peripheral	Caused or prolonged inpatient hospitalisation	Fingers feeling tight	ED treatment
Palpitations		Palpitations	
Vomiting		Vomiting, lack of control	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Took Zoloft for 2 days, also taking unspecified cardiovascular medications

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191166 **Seq:** 1
Reported: 08/10/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 93.00
Age: 45
DOB: 18/09/1958
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Chills Drug withdrawal syndrome	Required Visit to Doctor	The patient has been prescribed Zoloft for a number of years for depression. The patient has recently been reducing the dosage with the intention of stopping. Since this course of action, at times severe withdrawal reaction has occurred. Over a period of approximatelly 3 weeks, the patient has experienced dizzy spells (as frequent as 8 per hour), tingling feelings in his hands, nausia, chills, mood swings and "crawling skin".	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 100.0 Milligram 2 times Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has been prescribed Zoloft for a number of years for depression. The patient has recently been reducing the dosage with the intention of stopping the medication

Report Detail

Case Number: 191166 **Seq:** 1
Reported: 08/10/2003
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 93.00
Age: 45
DOB: 18/09/1958
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Formication Mood swings Nausea Paraesthesia			

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet	100.0	Milligram	2 times	Oral

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

Laboratory Investigations:

Additional Information:

The patient has been prescribed Zoloft for a number of years for depression. The patient has recently been reducing the dosage with the intention of stopping the medication

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191199 **Seq:** 1 **Gender:** M
Reported: 10/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 88Y
Onset Date: 05/09/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia	Given IV fluids.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet	50.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 09/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/10/2003	Creatinine		07/09/2003	0.05	
10/10/2003	Sodium		07/09/2003	128	
10/10/2003	Sodium		09/09/2003	122	

Additional Information:

Other drugs: Pantoprazole, Calcitriol, Dihydroxycholecalciferol and Aspirin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191230 **Seq:** 1 **Gender:** F
Reported: 13/10/2003 **Weight:**
Hospitalisation: **Age:** 99U
Onset Date: 03/10/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Irritability			
Poor quality sleep			
Staring			
Tremor neonatal		Baby developed shaking hands, irritability, poor sleep	
Psychomotor hyperactivity		Hyperactivity plus staring/no eye contact.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
25.0 Milligram Daily Breast milk transfer
Batch: **Started:** 01/10/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms settled after 4 days.
Baby experienced symptoms by breast milk transfer.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191245 **Seq:** 1 **Gender:** F
Reported: 13/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 62Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse Blood pressure decreased Depression Muscle rigidity Nausea	Caused or prolonged inpatient hospitalisation	Collapsed, rigidity bodily, nausea, blood pressure decreased, depression.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Alprazolam, Diazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191360 **Seq:** 1 **Gender:** F
Reported: 16/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	Hypotension, Hypoglycemia, Chronic fatigue syndrome, Abdominal pain,Hospitalization.	Mineralocorticoids
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Chronic fatigue syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

1.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191360 **Seq:** 1 **Gender:** F
Reported: 16/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191374 **Seq:** 1 **Gender:** F
Reported: 16/10/2003 **Weight:** 60.00
Hospitalisation: **Age:** 71
Onset Date: **DOB:** 06/11/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia	Required Visit to Doctor	Alopecia	

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 13/05/2003 **Stopped:** 30/09/2003

FLUOROURACIL (Suspected) **Reason:**

Cream 2.0 Dose Unspecified Daily Topical

Batch: **Started:** 01/09/2003 **Stopped:** 30/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191392 **Seq:** 1 **Gender:** M
Reported: 17/10/2003 **Weight:** 77.00
Hospitalisation: Admitted to hospital **Age:** 65
Onset Date: 08/09/2003 **DOB:** 30/05/1938
Outcome: Recovered 09/09/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Patient developed grand mal seizure.	
Inappropriate antidiuretic hormon	Caused or prolonged inpatient hospitalisation	Patient developed grand mal seizure.	
Atrial fibrillation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
50.0 Milligram 1 time
Batch: **Started:** 07/09/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/10/2003	Echocardiogram				
17/10/2003	Serum osmolality		08/09/2003	259	
17/10/2003	Sodium		08/09/2003	121	
17/10/2003	Urine Sodium		08/09/2003	80	
17/10/2003	Urine osmolality		08/09/2003	551	

Additional Information:

Patient also administered: Asasantin, Felodipine. On a background of heavy/Kava use (associated with excess water intake).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191618 **Seq:** 1 **Gender:** F
Reported: 27/10/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 91
Onset Date: 25/09/2003 **DOB:** 08/07/1912
Outcome: Recovered 30/09/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain	Severe	Back pain	
Myoclonus	Severe	Development of myoclonus .	Required Sedation and Valium.

Medicine Details:

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

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

TRAMAL SR (Suspected) **Reason:** Pain
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 26/09/2003

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 26/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zololt was increased from 50mg/daily to 100mg/daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191684 **Seq:** 1 **Gender:** M
Reported: 28/10/2003 **Weight:** 55.00
Hospitalisation: **Age:** 88Y
Onset Date: 19/10/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal impairment	Required Visit to Doctor	Sudden increase in confusion , GGT had increased from 100 to 178 over that period.	
Confusional state	Required Visit to Doctor		
Gamma-glutamyltransferase incr	Required Visit to Doctor		

Medicine Details:

ENALAPRIL MALEATE (Suspected) **Reason:** Essential benign hypertension
Tablet 2.5 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

CELECOXIB (Suspected) **Reason:** Pain
Capsule 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/10/2003

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 11/10/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/10/2003	Creatinine				
28/10/2003	GGT = SGGT =				

Additional Information:

Other drugs used: Panadeine and Betoptic.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191713 **Seq:** 1 **Gender:** F
Reported: 29/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction Blood folate decreased Emotional distress Optic ischaemic neuropathy Visual acuity reduced Visual field defect	Required Specialist Consultation	Photosensitivity, visual impairment, ischaemic optic neuropathy, fowlate low,visual field defect emotional distress.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

04/09/03: Magnetic Resonance Imaging: No abnormalities, tumours, tuberculum, meningioma, or multiple sclerosis.
Eye Test: test results, optometrist confirmed she was losing her vision.
Fluoroscein Angiogram: Losing vision, no glaucoma or retinal eye disease, tentative diagnosis of anterior ischaemic optic neuropathy in the right eye. Test date unspecified. Onset March or April 2003. Dose start date: 12/2003.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191782 **Seq:** 1
Reported: 31/10/2003
Hospitalisation:
Onset Date: 01/10/2003
Outcome: Recovered with sequelae

Gender: F
Weight: 0.00
Age: 85
DOB: 16/10/1917
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Life	Hyponatraemia	Fluid restriction.

Medicine Details:

METFORMIN HYDROCHLORIDE (Suspected) **Reason:** Diabetes mellitus
Tablet 1.0 Gram Daily Oral
Batch: **Started:** L TERM **Stopped:** 02/10/2003

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 23/09/2003 **Stopped:** 02/10/2003

KARVEZIDE 150/12.5 (Suspected) **Reason:** Congestive heart failure
150.0 Milligram Daily
Batch: **Started:** **Stopped:** contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Daonil, Karvezide, MS Contin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191821 **Seq:** 1 **Gender:** M
Reported: 03/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 86
Onset Date: **DOB:** 18/12/1916
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Orthostatic hypotension,extrapyramidal	The patients concomitant antihypertensive, frusemide, was also ceased. No other treatment was necessary.
Parkinsonism		Parkinsonian gait, tremor, muscle rigidity.	
Blood pressure decreased			
Extrapyramidal disorder			
Muscle rigidity			
Tremor			

Medicine Details:

FRUSEMIDE (Interaction) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Interaction) **Reason:** Schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 20/09/2003 **Stopped:** 20/10/2003

DIGOXIN (Other drug) **Reason:**
Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2003	Other data				

Additional Information:

Clozaril was reduced to 75mg and condition improved. Clozaril was increased again and condition worsened. Tremor continued as at 28/10/2003, and therefore the reporter believed the patient's underlying Parkinsonism was probably pre-existing. Initial starting dose of Clozaril was 25mg which was slowly increased to 100mg when reaction occurred.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191825 **Seq:** 1 **Gender:** F
Reported: 03/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 18Y
Onset Date: 11/10/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Treated in outpatient department only	Headache, dizzy spells, blacked out, fit, crying uncontrollable.	
Convulsion	Treated in outpatient department only		
Crying	Treated in outpatient department only		
Dizziness	Treated in outpatient department only		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/11/2003	Serum drug level				

Additional Information:

The patient received Zoloft 100mg per day for 15 months, then 150mg per day for two months, and then 50mg for the two weeks prior to reporting. The patient appeared to have been drinking, had drunk one glass of wine, one glass of spirits.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191825 **Seq:** 1 **Gender:** F
Reported: 03/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 18Y
Onset Date: 11/10/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness	Treated in outpatient department only		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

The patient received Zoloft 100mg per day for 15 months, then 150mg per day for two months, and then 50mg for the two weeks prior to reporting. The patient appeared to have been drinking, had drunk one glass of wine, one glass of spirits.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191965 **Seq:** 1 **Gender:** U
Reported: 07/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	Drug ineffective.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191972 **Seq:** 1 **Gender:** M
Reported: 07/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 23/10/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** 22/10/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient took Zoloft tablet (dose unspecified), in the afternoon on 22/10/03. The patient experienced a seizure at 2am on 23/10/03. The patient has a history of mild seizures. No further information provided.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191974 **Seq:** 1 **Gender:** M
Reported: 07/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Caused or prolonged inpatient hospitalisation	Paraesthesia of fingers, tingling mouth, paraesthesia foot, foot drop, muscle weakness, nerve conduction studies abnormal	
Muscular weakness	Caused or prolonged inpatient hospitalisation		
Nerve conduction studies abnorm	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/06/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Paracetamol and Acetylsalicylic acid.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191974 **Seq:** 1 **Gender:** M
Reported: 07/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Peroneal nerve palsy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/06/2003 **Stopped:**

Laboratory Investigations:

Additional Information:
Patient also taking Paracetamol and Acetylsalicylic acid.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 191975 **Seq:** 1 **Gender:** F
Reported: 07/11/2003 **Weight:** 56.00
Hospitalisation: **Age:** 34
Onset Date: 13/10/2003 **DOB:** 24/10/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angle closure glaucoma	Required Specialist Consultation	Patient experienced and exacerbation of anatomical narrow angle borderline glaucoma.	Opthalmologist will keep a close eye on the intraoccular pressure of her angles

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 09/09/2003 **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had a form of narrow angle associated intermittent occular hypertension and bilateral YAG (yttrium-aluminium-garnet) peripheral iridectomies in 2001.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 192071 **Seq:** 1 **Gender:** F
Reported: 11/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: 03/11/2003 **DOB:** 18/12/1954
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Disorientation Dizziness Hyperventilation Nausea Palpitations Tachycardia		Withdrawal reactions - nausea, dizziness, palpitations, tachycardia, hyperventilation, disorientations.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms have occurred on two seperate occasions - symptoms relieved by recommencing Zoloft on each occasion.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 192237 **Seq:** 1
Reported: 14/11/2003
Hospitalisation:
Onset Date: 16/09/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 24
DOB: 06/11/1978
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypocalcaemia	Caused or prolonged inpatient hospitalisation	Hypocalcaemia	Treated with iv Calcium.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**		
Tablet				Oral	
Batch:	**Started:**			**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia	
Tablet	37.5	Milligram	Daily	Oral	
Batch:	**Started:**	02/06/1999		**Stopped:**	Contin
SOLIAN (Suspected)			**Reason:**		
Tablet	200.0	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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 192325 **Seq:** 1 **Gender:** M
Reported: 19/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 85
Onset Date: 20/10/2003 **DOB:** 24/06/1918
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise	Caused or prolonged inpatient hospitalisation	Felt generally ill, nausea, urinary retention.	Zoloft ceased
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 20/10/2003 **Stopped:** 5 days

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Warfarin, Frusemide, Carvedilol, Candesartan Cilexetil, Allopurinol, Erythropoietin. History - heart failure, renal failure, atrial fibrillation, gout.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 192330 **Seq:** 1 **Gender:** F
Reported: 19/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 56Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cholelithiasis	Caused or prolonged inpatient hospitalisation	Gallstones, jaundice, lab test abnormal, rash, sore eyes, sleep difficult.	Admitted to hospital to have her gall stones removed. Therapy was ceased in Jul or Aug 2003.
Jaundice	Caused or prolonged inpatient hospitalisation		
Laboratory test abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 192337 **Seq:** 1 **Gender:** M
Reported: 19/11/2003 **Weight:** 85.00
Hospitalisation: **Age:** 38Y
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 - restless, agitated,	
Agitation	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRAMAL SR (Interaction) **Reason:**
400.0 Gram Daily
Batch: **Started:** 01/05/2003 **Stopped:** 01/06/2003

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 01/05/2003 **Stopped:** 01/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: E-C Aspirin, Omeprazole, Panadol.
Was taking up to 700mg Tramadol/day.

Report Detail

Case Number: 192337 **Seq:** 1 **Gender:** M
Reported: 19/11/2003 **Weight:** 85.00
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Restlessness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

TRAMAL SR (Interaction) **Reason:**
400.0 Gram Daily
Batch: **Started:** 01/05/2003 **Stopped:** 01/06/2003

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 01/05/2003 **Stopped:** 01/06/2003

Laboratory Investigations:

Additional Information:

Patient also administered: E-C Aspirin, Omeprazole, Panadol.
Was taking up to 700mg Tramadol/day.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 192427 **Seq:** 1 **Gender:** F
Reported: 24/11/2003 **Weight:** 56.00
Hospitalisation: **Age:** 21
Onset Date: 12/11/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash papular		Patient developed papular rash, beginning on face spreading to back and abdomen.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet Dose Unspecified Oral
Batch: **Started:** 07/11/2003 **Stopped:** 17/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction within one week. Previous allergic reaction to anaesthetic and skin reaction with infection.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 192463 **Seq:** 1 **Gender:** F
Reported: 24/11/2003 **Weight:** 65.00
Hospitalisation: **Age:** 40Y
Onset Date: **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:

ZOLOFT (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.

Report Detail

Case Number: 192689 **Seq:** 1 **Gender:** M
Reported: 01/12/2003 **Weight:** 95.00
Hospitalisation: **Age:** 53
Onset Date: 16/09/2003 **DOB:**
Outcome: Recovered 17/09/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Required Visit to Doctor	Insomnia, suggestive elements of delirium, myoclonic jerks of legs, suggestive of serotonin syndrome.	Cease Tramal and Zoloft.
Delirium	Required Visit to Doctor		
Myoclonus	Required Visit to Doctor		
Serotonin syndrome	Required Visit to Doctor		

Medicine Details:

TRAMAL (Interaction) **Reason:** Pain
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 07/09/2003 **Stopped:** 16/09/2003

ZOLOFT (Interaction) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 07/09/2003 **Stopped:** 16/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Valtrex Valacyclovir, Nexium, Ceftriaxone, Rulide, Panadol, Prednisolone.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 192793 **Seq:** 1 **Gender:** F
Reported: 03/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 27/10/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome neona Neonatal disorder		Drug withdrawal syndrome. Neonatal disorder NOS - abnormality.	

Medicine Details:

RISPERDAL (Suspected) **Reason:**
Tablet 4.0 Milligram Daily Intrauterine
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

MOCLOBEMIDE (Suspected) **Reason:**
1.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Marcain and Fentanyl.
Baby was exposed from 20+ weeks. The baby experienced withdrawl symptoms (from risperidone) for 2 days, on days 3 and 4, however, did not require medication to control it.

Report Detail

Case Number: 192955 **Seq:** 1 **Gender:** F
Reported: 08/12/2003 **Weight:** 50.00
Hospitalisation: **Age:** 40
Onset Date: 28/11/2003 **DOB:** 15/07/1963
Outcome: Recovered 04/12/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fall	Required Visit to Doctor	Patient fell when getting up during night , required 3 stitches, was agitated and confused, reflux symptoms.	
Agitation	Required Visit to Doctor		
Confusional state	Required Visit to Doctor		
Reflux oesophagitis	Required Visit to Doctor		

Medicine Details:

PANAMAX (Other drug) **Reason:** Pain
1.5 Gram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Pain
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 22/11/2003 **Stopped:** 29/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193010 **Seq:** 1 **Gender:** M
Reported: 10/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 58Y
Onset Date: 18/11/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bronchospasm	Severe	Bronchospasm.	Zoloft therapy was discontinued and events are resolved.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Galantamine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193135 **Seq:** 1 **Gender:** F
Reported: 15/12/2003 **Weight:** 116.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 27/08/2003 **DOB:** 20/08/1951
Outcome: Recovered 01/10/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizzy and lightheaded	
Polydipsia		Drinking water	
Agitation		Very agitated	
Aggression			
Blood sodium decreased			
Confusional state			
Depersonalisation			
Fatigue			
Hallucination			
Mania			

Medicine Details:

TERTROXIN (Other drug) **Reason:** Myxedema
60.0 Microgram Daily
Batch: **Started:** 01/01/1999 **Stopped:** 27/08/2003

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
Tablet 50.0 Microgram Daily Oral
Batch: **Started:** 01/01/1976 **Stopped:** 27/08/2003

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 01/04/1997 **Stopped:** 27/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The start date of Zoloft is not necessarily accurate but indicates that the drug was started some time in the month. The start date for both Tertroxin and thyroxine are not necessarily accurate but indicates that the drug was started some time in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193135 **Seq:** 1 **Gender:** F
Reported: 15/12/2003 **Weight:** 116.00
Hospitalisation: Admitted to hospital **Age:** 52
Onset Date: 27/08/2003 **DOB:** 20/08/1951
Outcome: Recovered 01/10/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mental disorder Psychotic disorder Thinking abnormal Thirst	Life		Hospitalisation, medical/psychatric consult

Medicine Details:

TERTROXIN (Other drug) **Reason:** Myxedema
60.0 Microgram Daily
Batch: **Started:** 01/01/1999 **Stopped:** 27/08/2003

THYROXINE SODIUM (Other drug) **Reason:** Myxedema
Tablet 50.0 Microgram Daily Oral
Batch: **Started:** 01/01/1976 **Stopped:** 27/08/2003

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 01/04/1997 **Stopped:** 27/08/2003

Laboratory Investigations:

Additional Information:

The start date of Zoloft is not necessarily accurate but indicates that the drug was started some time in the month. The start date for both Tertroxin and thyroxine are not necessarily accurate but indicates that the drug was started some time in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193136 **Seq:** 1 **Gender:** F
Reported: 15/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 61Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation	Increased liver function test, abdominal pain, albumin decreased and creatinine decreased.	
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Blood albumin decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 150.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2003	Albumin		19/11/2003	Unk	
15/12/2003	Bilirubin		19/11/2003	23	
15/12/2003	Creatinine		19/11/2003	Unk	
15/12/2003	GGT = SGGT =		19/11/2003	127	
15/12/2003	Other data				
15/12/2003	SAP = ALP		19/11/2003	37	

Additional Information:

Report Detail

Case Number: 193136 **Seq:** 1 **Gender:** F
Reported: 15/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 61Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatinine decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 150.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193137 **Seq:** 1 **Gender:** F
Reported: 15/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 82
Onset Date: 17/11/2003 **DOB:** 12/01/1921
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Insomnia		Hyponatremia and insomnia	Zoloft was ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 11/11/2003 **Stopped:** 17/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2003	Sodium	135 - 145	10/11/2003	135	
15/12/2003	Sodium	135 - 145	17/11/2003	117	

Additional Information:

Patient was also taking zopiclone, paracetamol, celecoxib, ramipril, amlodipine and Asasantin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193198 **Seq:** 1 **Gender:** F
Reported: 16/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 88
Onset Date: 18/08/2003 **DOB:** 10/06/1915
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia	Sertraline ceased

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 07/08/2003 **Stopped:** 21/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2003	Sodium		07/08/2003	137	
16/12/2003	Sodium		21/08/2003	129	

Additional Information:

Patient also administered: Metformin, Aspirin, Enalapril, Donepezil, Atenolol, Paracetamol, Ural sachets, Potassium Chloride, Latanaprost Eye drops, Gliclazide.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193208 **Seq:** 1 **Gender:** F
Reported: 16/12/2003 **Weight:** 0.00
Hospitalisation: **Age:** 61
Onset Date: 29/09/2003 **DOB:** 27/05/1942
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatraemia.	Sertraline ceased

Medicine Details:

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

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 16/09/2003 **Stopped:** 29/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193440 **Seq:** 1 **Gender:** M
Reported: 22/12/2003 **Weight:** 58.00
Hospitalisation: **Age:** 94
Onset Date: 16/08/2003 **DOB:** 30/07/1909
Outcome: Recovered 23/08/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Visit to Doctor	Serotonin syndrome, confusion, muscle twitching, diarrhoea, hallucinations, faintness, falls.	Zoloft and Tramal ceased.
Confusional state	Required Visit to Doctor		
Diarrhoea	Required Visit to Doctor		
Dizziness	Required Visit to Doctor		
Fall	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Interaction) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 21/08/2003

TRAMAL (Interaction) **Reason:** Pain
Capsule 50.0 Milligram Daily Oral
Batch: **Started:** 15/08/2003 **Stopped:** 21/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Soflax, Somac and Fybogel.

Report Detail

Case Number: 193440 **Seq:** 1 **Gender:** M
Reported: 22/12/2003 **Weight:** 58.00
Hospitalisation: **Age:** 94
Onset Date: 16/08/2003 **DOB:** 30/07/1909
Outcome: Recovered 23/08/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Required Visit to Doctor		
Muscle twitching	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Interaction) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 21/08/2003

TRAMAL (Interaction) **Reason:** Pain
Capsule 50.0 Milligram Daily Oral
Batch: **Started:** 15/08/2003 **Stopped:** 21/08/2003

Laboratory Investigations:

Additional Information:
Patient also taking Soflax, Somac and Fybogel.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193442 **Seq:** 1 **Gender:** M
Reported: 22/12/2003 **Weight:** 70.00
Hospitalisation: **Age:** 30
Onset Date: 01/12/2003 **DOB:** 30/05/1973
Outcome: Recovered with sequelae 06/12/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching	Required Visit to Doctor	Involuntary muscle twitching around upper lip. Persistent and obvious.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 25/11/2003 **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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193582 **Seq:** 1 **Gender:** F
Reported: 06/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: 26/12/2003 **DOB:** 08/09/1954
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood pressure decreased	Required Visit to Doctor	Drop in BP 78/48.	Prednisolone 50mg daily 3 days and reduced.
Peripheral coldness	Required Visit to Doctor	Gold extremities	
Skin disorder	Required Visit to Doctor	Salp inflammation all over -flakey scalp.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 26/12/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Renitec Plus, Tenormin, Actonel.
patient took 25mg 21-25/12/03, 50mg 26-27/12/03.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193583 **Seq:** 1 **Gender:** F
Reported: 06/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 54
Onset Date: 26/12/2003 **DOB:** 24/11/1949
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Required Visit to Doctor	Anxiety and panic attacks.	Ceased Zoloft.
Panic attack	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Batch: **Started:** 23/12/2003 **Stopped:** 28/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 193624 **Seq:** 1
Reported: 06/01/2004
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2003
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 66
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia	Caused or prolonged inpatient hospitalisation	Gynaecomastia.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 150.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/01/2004	Other data				

Additional Information:

Receiving Zoloft 150mg for major depression for the past three years. Zoloft therapy has ceased and the gynacomastia has not resolved. Zoloft reduced to 50mg before being discontinued. Other drugs: Karvea and Vioxx.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194038 **Seq:** 1 **Gender:** M
Reported: 22/01/2004 **Weight:** 50.00
Hospitalisation: **Age:** 80
Onset Date: 12/01/2004 **DOB:** 26/01/1923
Outcome: Recovered 14/04/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Required Visit to Doctor	Hallucinations.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 10/01/2004 **Stopped:** 12/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Caltrate, Ranitidine, Warfarin, Quinate and Panadeine Forte. Dementia proved to adverse psycho symptoms with medications.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194097 **Seq:** 1 **Gender:** M
Reported: 27/01/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	Psychotic episode "kill yourself and [illegible]"	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194128 **Seq:** 1 **Gender:** F
Reported: 29/01/2004 **Weight:** 65.00
Hospitalisation: **Age:** 81
Onset Date: 01/12/2003 **DOB:** 15/12/1921
Outcome: Recovered 13/12/2003 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 01/12/2003

KARVEZIDE 300/12.5 (Suspected) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:** 01/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/01/2004	Sodium		01/12/2003	113	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194340 **Seq:** 1
Reported: 04/02/2004
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 25
DOB: 02/12/1978
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Drug ineffective Intentional self-injury Suicide attempt		Suicidal ideation. Deliberate self harm - overdose, cut wrists, tried to hang herself. Suicide attempts. Drug ineffective.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 200.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194401 **Seq:** 1 **Gender:** M
Reported: 09/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 83Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Drug ineffective	Life Life	Suicide attempt, drug ineffective, lack of	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily
Batch: **Started:** 21/08/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Acetylsalicylic acid, Cyclophosphamide, Lasix, Amlodipine besilate, Prednisolone, Fexofenadine hydrochloride, Sotalol hydrochloride, Mirtazapine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194411 **Seq:** 1 **Gender:** M
Reported: 09/02/2004 **Weight:** 70.00
Hospitalisation: **Age:** 21
Onset Date: 21/06/2001 **DOB:** 16/12/1979
Outcome: Recovered with sequelae 18/07/2001 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Delusion Drug withdrawal syndrome Hypervigilance Psychotic disorder	Required Visit to Doctor	Patient developed acute psychotic illness.	Given Risperidone.

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 21/12/1999 L TERM **Stopped:** 18/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Within days of stopping Sertraline.

Report Detail

Case Number: 194521 **Seq:** 1 **Gender:** F
Reported: 11/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 84
Onset Date: 05/02/2004 **DOB:** 30/08/1919
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia - asymptomatic, falling down, debility.	Stopped Zoloft (Zoloft slowly reduced, then stopped 08/02/2004)
Asthenia	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 08/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Caltrate, Karvea, Naprosyn SR, Oroxine, Plavix, Premarin, Zantac.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194606 **Seq:** 1 **Gender:** F
Reported: 16/02/2004 **Weight:** 63.00
Hospitalisation: **Age:** 81
Onset Date: 07/11/2003 **DOB:** 15/12/1921
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Fall Gait disturbance		Hyponatraemia, difficulty in walking, fall.	Zoloft ceased. Patient received sodium replacement.

Medicine Details:

KARVEZIDE 300/12.5 (Other drug) **Reason:** Essential benign hypertension
Tablet Oral
Batch: **Started:** 01/01/2001 **Stopped:** 01/12/2003

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 6 years

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/02/2004	Sodium	136 - 146	01/12/2003	113	
16/02/2004	Sodium	136 - 146	10/12/2003	133	

Additional Information:

History: Osteoarthritis and Psoriasis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194616 **Seq:** 1
Reported: 16/02/2004
Hospitalisation: Admitted to hospital
Onset Date: 09/01/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 90
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise	Caused or prolonged inpatient hospitalisation	Unwell, shakiness, fever, congestive heart failure, blod pressure increased, twitching, ischeamia, creatine kinase increased, serotonin syndrome - suspected.	Karvea (irbesartan).
Blood creatine phosphokinase in	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Tablet 50.0 Milligram Daily

Batch: **Started:** 09/10/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/02/2004	Creatine				
16/02/2004	Electrocardiograph				

Additional Information:

Patient also administered: Atorvastatin, Ramipril, Atenolol.
The patient has a history of ischaemic heart disease and had a myocardial infarction (MI) 12 years prior to reporting.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194616 **Seq:** 1
Reported: 16/02/2004
Hospitalisation: Admitted to hospital
Onset Date: 09/01/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 90
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood pressure increased	Caused or prolonged inpatient hospitalisation		
Cardiac failure congestive	Caused or prolonged inpatient hospitalisation		
Ischaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 50.0 Milligram Daily
Batch: **Started:** 09/10/2003 **Stopped:**

Laboratory Investigations:

Additional Information:

Patient also administered: Atorvastatin, Ramipril, Atenolol.
The patient has a history of ischaemic heart disease and had a myocardial infarction (MI) 12 years prior to reporting.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194616 **Seq:** 1
Reported: 16/02/2004
Hospitalisation: Admitted to hospital
Onset Date: 09/01/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 90
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 50.0 Milligram Daily
Batch: **Started:** 09/10/2003 **Stopped:**

Laboratory Investigations:

Additional Information:

Patient also administered: Atorvastatin, Ramipril, Atenolol.
The patient has a history of ischaemic heart disease and had a myocardial infarction (MI) 12 years prior to reporting.

Report Detail

Case Number: 194616 **Seq:** 1
Reported: 16/02/2004
Hospitalisation: Admitted to hospital
Onset Date: 09/01/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 90
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Tablet 50.0 Milligram Daily

Batch: **Started:** 09/10/2003 **Stopped:**

Laboratory Investigations:

Additional Information:

Patient also administered: Atorvastatin, Ramipril, Atenolol.
The patient has a history of ischaemic heart disease and had a myocardial infarction (MI) 12 years prior to reporting.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194622 **Seq:** 1 **Gender:** F
Reported: 16/02/2004 **Weight:** 65.00
Hospitalisation: **Age:** 21
Onset Date: 06/02/2004 **DOB:** 26/03/1982
Outcome: Recovered 08/02/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Required Visit to Doctor	Involuntary muscle movements - head, arms and legs which lasted 2 hours. Anxiety.	Reduce and cease Sertraline.
Anxiety	Required Visit to Doctor		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily
Batch: **Started:** 06/02/2004 **Stopped:** 07/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous exposure to Citalopram - extreme sedation.

Report Detail

Case Number: 194662 **Seq:** 1 **Gender:** F
Reported: 16/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 76Y
Onset Date: 27/01/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush Drug withdrawal syndrome Panic attack		Feeling of hot flushes - waves of heat over whole body, panic attack, withdrawal reaction.	Xanax was not effective.

Medicine Details:

TENORMIN (Other drug) **Reason:**
50.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** Contin

AVANZA (Suspected) **Reason:**
Tablet 30.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 25/01/2004

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily
Batch: **Started:** 26/01/2004 **Stopped:** 28/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194685 **Seq:** 1 **Gender:** F
Reported: 17/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 84
Onset Date: 09/02/2004 **DOB:** 26/10/1919
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous	Required Visit to Doctor	Red erythematous rash on trunk, back and right thigh.	Given Phenergan.

Medicine Details:

CARTIA (Suspected)			**Reason:**		
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	10/02/2004
OROXINE (Suspected)			**Reason:**	Thyroiditis	
Tablet	50.0	Microgram	Daily		Oral
Batch:	**Started:**			**Stopped:**	10/02/2004
ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	10/02/2004
OSTELIN 1000 (Suspected)			**Reason:**		
Capsule	25.0	Microgram	Daily		Oral
Batch:	**Started:**	06/02/2004		**Stopped:**	10/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 194685 **Seq:** 1
Reported: 17/02/2004
Hospitalisation:
Onset Date: 09/02/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 84
DOB: 26/10/1919
Causality: Causality possible

Reaction Detail

Medicine Details:

CALTRATE (Suspected)			**Reason:**	
Tablet	600.0	Milligram	Daily	Oral
Batch:	**Started:**	06/02/2004	**Stopped:**	10/02/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194932 **Seq:** 1 **Gender:** M
Reported: 26/02/2004 **Weight:** 103.00
Hospitalisation: **Age:** 46
Onset Date: 19/02/2004 **DOB:** 14/05/1957
Outcome: Recovered 20/02/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient presented with 3 day history of pyrexia to 41C, agitation, increased myoclonic jerks and hyperventilation.	IV rehydration and reducing Sertraline dose to 100mg.
Agitation	Caused or prolonged inpatient hospitalisation		
Hyperventilation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Interaction) **Reason:** Unspecified schizophrenia
Tablet 650.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 15/12/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pathology -> elevated CK, Trop I - ND, anaemia and thrombocytopenia. Patient also taking Clonazepam, Omeprazole, Propranolol and Ferrous Sulphate.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 194932 **Seq:** 1 **Gender:** M
Reported: 26/02/2004 **Weight:** 103.00
Hospitalisation: **Age:** 46
Onset Date: 19/02/2004 **DOB:** 14/05/1957
Outcome: Recovered 20/02/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myoclonus	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Interaction) **Reason:** Unspecified schizophrenia

Tablet 650.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:**

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 15/12/2003 **Stopped:**

Laboratory Investigations:

Additional Information:

Pathology -> elevated CK, Trop I - ND, anaemia and thrombocytopenia. Patient also taking Clonazepam, Omeprazole, Propranolol and Ferrous Sulphate.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195020 **Seq:** 1 **Gender:** M
Reported: 01/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: 31/01/2004 **DOB:** 15/06/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Irritability Headache Hot flush Insomnia Serotonin syndrome		Irritable, hot flushes, headache, insomnia, serotonin syndrome (suspected).	

Medicine Details:

CELECOXIB (Other drug) **Reason:** Other rheumatoid arthritis
Capsule 400.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 195042 **Seq:** 1 **Gender:** F
Reported: 01/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 72Y
Onset Date: 21/09/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Confusional state Hallucination, visual Hyperreflexia Serotonin syndrome		Sweating increased, limb defect - hyperflexia, confusion, visual hallucinations, serotonin syndrome.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 50.0 Milligram Daily
Batch: **Started:** 20/08/2003 **Stopped:** 20/11/2003

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain
Tablet 200.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Prednisolone, Atorvastatin, Omeprazole.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195138 **Seq:** 1 **Gender:** F
Reported: 05/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Miscarriage (after medication ceased).	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet Dose Unspecified
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient stopped Zoloft therapy and had a miscarriage in Mar2003. The patient had another miscarriage before a successful birth to a baby girl. At the time of reporting the patient was experiencing anxiety and insomnia and has been prescribed Zoloft again.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195144 **Seq:** 1 **Gender:** F
Reported: 05/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia, generalized illness.	
Malaise	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195726 **Seq:** 1 **Gender:** M
Reported: 19/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 15/03/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Depression Hallucination, auditory Obsessive-compulsive disorder Salivary hypersecretion		Convulsion (shakes and falls), auditory hallucinations, obsessive compulsive disorder, depression.	Clozaril decreased to 600mg daily, commenced on Sodium Valproate

Medicine Details:

CLOZARIL (Interaction) **Reason:** Unspecified schizophrenia

Tablet 700.0 Milligram Daily Oral

Batch: **Started:** 19/06/2003 **Stopped:**

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/03/2004	Electroencephalog				
19/03/2004	Other data				

Additional Information:

There were a total of four episodes of seizures

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195750 **Seq:** 1 **Gender:** U
Reported: 19/03/2004 **Weight:** 67.00
Hospitalisation: **Age:** 78
Onset Date: 12/03/2004 **DOB:** 22/05/1925
Outcome: Recovered 15/03/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia	Patient stopped both medications - restarted on Coversyl 4mg alone and changed Sertraline to Olanzepine 5mg

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

COVERSYL PLUS (Suspected) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/03/2004	Sodium				

Additional Information:

Other drugs: Esomeprazole, Metoclopramide and Clopidogrel.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195770 **Seq:** 1 **Gender:** F
Reported: 19/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 10/06/2001 **DOB:** 12/09/1967
Outcome: Death, maybe drug 13/06/2001 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Severe	Agitation, abnormal ("very floaty"), concentration ability impaired	Reaction was not treated
Disturbance in attention	Severe	Agitation, feeling abnormal ("very floaty"), concentration ability impaired	Reaction was not treated
Feeling abnormal	Severe	Agitation, feeling abnormal ("very floaty"), concentration ability impaired	Reaction was not treated
Death	Severe	Agitation, feeling abnormal ("very floaty"), concentration ability impaired. Death	Reaction was not treated

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram 1 time Oral
Batch: **Started:** 10/06/2001 **Stopped:** 13/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 195832 **Seq:** 1 **Gender:** F
Reported: 22/03/2004 **Weight:** 72.00
Hospitalisation: **Age:** 87
Onset Date: 09/03/2004 **DOB:** 22/09/1916
Outcome: Recovered 10/03/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia.	Sertraline and Indapamide
Circulatory collapse	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:**
Tablet 1.5 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/03/2004	Sodium				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195840 **Seq:** 1 **Gender:** F
Reported: 22/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: 04/03/2004 **DOB:** 07/09/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthma	Caused or prolonged inpatient hospitalisation	Severe asthmatic attack, neuropathy, agitation, diarrhoea.	Zoloft stopped.
Agitation	Life		
Anxiety	Life		
Diarrhoea	Life		
Hypokalaemia	Life		
Intentional overdose	Life		
Neuropathy peripheral	Life		
Pruritus	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 27/02/2002 L TERM **Stopped:** 02/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/03/2004	Potassium	3.5 - 5.5	31/12/2003	2.8	
22/03/2004	Potassium	3.5 - 5.5	02/01/2004	3.0	
22/03/2004	Potassium	3.5 - 5.5	14/01/2004	3.7 (on Slow K)	
22/03/2004	Potassium	3.5 - 5.5	09/02/2004	3.8 (on Slow K	

Additional Information:

Medical history: Depression and anxiety. Other drug therapy seretide, clonazepam, ventolin, slow K, montelukast.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195840 **Seq:** 1 **Gender:** F
Reported: 22/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 48
Onset Date: 04/03/2004 **DOB:** 07/09/1955
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal failure	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 27/02/2002 L TERM **Stopped:** 02/02/2004

Laboratory Investigations:

Additional Information:

Medical history: Depression and anxiety. Other drug therapy seretide, clonazepam, ventolin, slow K, montelukast.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 195974 **Seq:** 1 **Gender:** F
Reported: 26/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Accidental overdose Disorientation Feeling abnormal Hypersensitivity Medication error		Accidental overdose, hypersensitivity, disorientation, feeing abnormal, medication error, spaced out.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 800.0 Milligram 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft (sertraline) 400mg as prescribed by her psychiatrist.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196019 **Seq:** 1
Reported: 29/03/2004
Hospitalisation:
Onset Date: 17/03/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 86
DOB: 21/09/1917
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Confused, dizzy, hyponatremia,	
Fall	Caused or prolonged inpatient hospitalisation	Fall resulted in fractured neck of femur	
Dizziness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 13/03/2004 **Stopped:** 17/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/03/2004	Sodium				

Additional Information:

Patient was also taking trimethoprim and Aspirin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196019 **Seq:** 1 **Gender:** F
Reported: 29/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 86
Onset Date: 17/03/2004 **DOB:** 21/09/1917
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Caused or prolonged inpatient hospitalisation		
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 13/03/2004 **Stopped:** 17/03/2004

Laboratory Investigations:

Additional Information:
Patient was also taking trimethoprim and Aspirin.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196060 **Seq:** 1 **Gender:** F
Reported: 29/03/2004 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 20Y
Onset Date: 29/02/2004 **DOB:**
Outcome: Unknown 29/02/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Caused or prolonged inpatient hospitalisation	Patient became breathless, experienced increasing difficulty in breathing and suffered an episode of delirium.	
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

DIANE-35 ED (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 27/02/2004 S TERM **Stopped:** 29/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:
Diane

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196061 **Seq:** 1 **Gender:** U
Reported: 29/03/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		Serotonin syndrome.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196170 **Seq:** 1 **Gender:** F
Reported: 02/04/2004 **Weight:** 56.00
Hospitalisation: **Age:** 27Y
Onset Date: 25/03/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Required Visit to Doctor	Tachycardia, palpitations, watery oily diarrhoea, flatulence, orange yellow in colour.	Ceased drug.
Diarrhoea	Required Visit to Doctor		
Flatulence	Required Visit to Doctor		
Palpitations	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 25/03/2004 **Stopped:** 25/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs: Stilnox and Diane 35 ED. History: Patient having LFT's colonoscopy previously.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196223 **Seq:** 1
Reported: 05/04/2004
Hospitalisation:
Onset Date: 08/03/2004
Outcome: Not yet recovered

Gender: M
Weight: 76.00
Age: 64
DOB: 08/07/1939
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysarthria	Caused or prolonged inpatient hospitalisation	Slurred speech, blurred vision, muscle weakness, dry mouth, tachycardia, agitation, delusional, bladder refused to work naturally, numbness in right foot, lack of concentration.	Patient had to be catherterised. Xanax stopped. Required a visit to doctor.
Agitation	Required Visit to Doctor		
Asthenia	Required Visit to Doctor		
Delusional disorder, unspecified t	Required Visit to Doctor		

Medicine Details:

XANAX (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 25/02/2004 **Stopped:** 12/03/2004

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 18/02/2004 **Stopped:** 20/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 196223 **Seq:** 1
Reported: 05/04/2004
Hospitalisation:
Onset Date: 08/03/2004
Outcome: Not yet recovered

Gender: M
Weight: 76.00
Age: 64
DOB: 08/07/1939
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disturbance in attention	Required Visit to Doctor		
Dry mouth	Required Visit to Doctor		
Hypoaesthesia	Required Visit to Doctor		
Tachycardia	Required Visit to Doctor		
Vision blurred	Required Visit to Doctor		

Medicine Details:

XANAX (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 25/02/2004 **Stopped:** 12/03/2004

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 18/02/2004 **Stopped:** 20/03/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196240 **Seq:** 1 **Gender:** M
Reported: 05/04/2004 **Weight:** 90.00
Hospitalisation: **Age:** 54
Onset Date: 13/03/2004 **DOB:** 23/10/1949
Outcome: Recovered 14/03/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Anxiety Suicidal ideation		Rapid onset of depression with severe feelings of suicidal tendencies. Within three hours depression had moved to major anxiety and he ran from his family and home. He felt the need to remove himself from all outside stimulus and moved to a local park and sat for close to five hours until anxiety ceased.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram 1 time Oral

Batch: **Started:** 13/03/2004 **Stopped:** 13/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196365 **Seq:** 1
Reported: 08/04/2004
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 52
DOB: 07/08/1951
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Paraesthesia		Withdrawal reaction, electric shock	

Medicine Details:

ATROVENT FORTE (Other drug) **Reason:** Smoker

Inhalation 4.0 Dose Unspecified Daily

Batch: **Started:** L TERM **Stopped:** contin

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

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 196467 **Seq:** 1 **Gender:** M
Reported: 14/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: **DOB:**
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug interaction Death Drug toxicity Intentional overdose		Drug interaction, drug toxicity due to intentional overdose, death.	Given Charcoal.

Medicine Details:

MOCLOBEMIDE (Interaction)	**Reason:**	
Batch:	**Started:**	**Stopped:**
SERTRALINE HYDROCHLORIDE (Interaction)	**Reason:**	
Batch:	**Started:**	**Stopped:**
PIMOZIDE (Interaction)	**Reason:**	
Batch:	**Started:**	**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/04/2004	Biochemistry				
14/04/2004	Haematology				
14/04/2004	Other data				

Additional Information:

J.Forensic Science 1997, 42(5): 951-953.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196739 **Seq:** 1
Reported: 22/04/2004
Hospitalisation:
Onset Date: 18/03/2004
Outcome: Not yet recovered

Gender: F
Weight: 90.00
Age: 51
DOB: 21/10/1952
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthritis		Arthritis aggravated.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 18/03/2004 **Stopped:** 19/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pre-existing asthritis. Also seen in other patients, similar history.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196884 **Seq:** 1 **Gender:** F
Reported: 29/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 75Y
Onset Date: 13/12/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation	Panic and anxiety, shakey, had seizure and collapsed, unconcious on arrival at hospital	Dilantin 300mg/d
Anxiety	Caused or prolonged inpatient hospitalisation		
Circulatory collapse	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 23/11/2003 **Stopped:** 13/12/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy: ventolin, atrovent, flixotide, pariet.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 196884 **Seq:** 1 **Gender:** F
Reported: 29/04/2004 **Weight:** 0.00
Hospitalisation: **Age:** 75Y
Onset Date: 13/12/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 23/11/2003 **Stopped:** 13/12/2003

Laboratory Investigations:

Additional Information:

Other drug therapy: ventolin, atrovent, flixotide, pariet.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197043 **Seq:** 1 **Gender:** M
Reported: 06/05/2004 **Weight:** 80.00
Hospitalisation: **Age:** 66
Onset Date: 24/03/2004 **DOB:** 30/03/1937
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Impaired gastric emptying	Caused or prolonged inpatient hospitalisation	Gastroparesis, large amount of food in stomach despite fasting for previous 12 hours	Ceased Ranitidine and begain Somac.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Dose Unspecified Oral
Batch: **Started:** **Stopped:**

ZANTAC (Suspected) **Reason:** Other diseases of esophagus
300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ARICEPT (Suspected) **Reason:** Presenile dementia
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

EPILIM (Suspected) **Reason:** Convulsions
Tablet 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 197043 **Seq:** 1

Reported: 06/05/2004

Hospitalisation:

Onset Date: 24/03/2004

Outcome: Unknown

Gender: M

Weight: 80.00

Age: 66

DOB: 30/03/1937

Causality: Causality possible

Reaction Detail

Medicine Details:

CABASER (Suspected) **Reason:**

Tablet 2.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197118 **Seq:** 1 **Gender:** F
Reported: 07/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood sodium decreased	Caused or prolonged inpatient hospitalisation	Sodium low, confusion, falling down	Zoloft ceased.
Confusional state	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197183 **Seq:** 1
Reported: 10/05/2004
Hospitalisation:
Onset Date: 08/04/2004
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 54
DOB: 28/05/1949
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Emotional distress	Caused or prolonged inpatient hospitalisation	Distress, screaming, speech loss and tremor limb, tremor would go from one arm to the other, then to both legs, depression aggravated.	Required a visit to doctor. Valium given. Zoloft ceased
Aphasia	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 08/04/2004 **Stopped:** 23/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced on zoloft 50mg on 08/04/04. Dose increased to 100mg on 15/04/04 and 150mg on 20/04/04 for 2 days and then 100mg twice a day.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197183 **Seq:** 1 **Gender:** F
Reported: 10/05/2004 **Weight:** 63.00
Hospitalisation: **Age:** 54
Onset Date: 08/04/2004 **DOB:** 28/05/1949
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Screaming	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 08/04/2004 **Stopped:** 23/04/2004

Laboratory Investigations:

Additional Information:

Patient commenced on zoloft 50mg on 08/04/04. Dose increased to 100mg on 15/04/04 and 150mg on 20/04/04 for 2 days and then 100mg twice a day.

Report Detail

Case Number: 197184 **Seq:** 1 **Gender:** M
Reported: 10/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 12/04/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disorientation Disturbance in attention Muscle twitching		Patient experienced disorentation, feeling like he had "two heads", felt like he was going on or coming off the medication for the first time, body felt slow, minor twitches and he had a minor car accident.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197352 **Seq:** 1 **Gender:** F
Reported: 14/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Miscarriage	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet | Dose Unspecified | Oral
Batch: **Started:** S TERM **Stopped:**

REDUCTIL (Suspected) **Reason:**
Capsule | Dose Unspecified | Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197359 **Seq:** 1
Reported: 14/05/2004
Hospitalisation: Admitted to hospital
Onset Date: 06/01/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 85
DOB: 06/07/1918
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	Nausea and vomiting	Zoloft ceased
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Zolpidem, Sotalol, Perindopril, Esomeprazole, Clopidogrel, Atorvastatin and Prochlorperazine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197390 **Seq:** 1 **Gender:** F
Reported: 17/05/2004 **Weight:** 63.00
Hospitalisation: **Age:** 26
Onset Date: 15/04/2004 **DOB:** 14/07/1977
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Feeling abnormal	Required Visit to Doctor	Sensation of being pulled along- not "out of body experience".	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No reaction on 50mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197467 **Seq:** 1 **Gender:** F
Reported: 20/05/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Abdominal pain upper Abortion spontaneous Anorexia Diarrhoea Insomnia		Shakiness, stomach pain, diarrhoea, appetite lost, sleep difficult and miscarriage.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 10 weeks

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient then found out she was six weeks pregnant and so was taken off Zoloft. The patient had a miscarriage at nine weeks.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197510 **Seq:** 1 **Gender:** F
Reported: 21/05/2004 **Weight:** 60.00
Hospitalisation: **Age:** 28
Onset Date: 05/05/2004 **DOB:** 08/09/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Lactorrhoea from 1 nipple.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** 02/12/2003 **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/05/2004	Prolactin				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197835 **Seq:** 1 **Gender:** M
Reported: 03/06/2004 **Weight:** 70.00
Hospitalisation: **Age:** 77
Onset Date: 21/05/2004 **DOB:** 11/07/1926
Outcome: Recovered 26/05/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Patient developed hyponatraemia.	Stopped sertraline.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/06/2004	Sodium		21/05/2004	128	
03/06/2004	Sodium		23/05/2004	135	

Additional Information:

Other drugs taken: Ventolin, Oxazepam, Quinine, Amiodarone, Clexane. Patient admitted for chest pain - random UEBC - discover hyponatraemia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197859 **Seq:** 1 **Gender:** F
Reported: 03/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 65Y
Onset Date: 01/01/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin burning sensation Abdominal pain upper Anxiety Asthenia Dyspnoea Hypoaesthesia Paraesthesia Vomiting		Malaise, burning all over body, particularly head, trouble catching breath, numbness in hands, tingling in hands and feet, no energy, weakness, anxiety worse, vomiting, nausea and pain in stomach.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/09/2003 **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 01/12/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had had ECT therapy for about 10 months.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197874 **Seq:** 1 **Gender:** F
Reported: 04/06/2004 **Weight:** 62.60
Hospitalisation: **Age:** 75
Onset Date: 22/05/2004 **DOB:** 20/12/1928
Outcome: Recovered 29/05/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension	Required Visit to Doctor	'Pounding' sensation in both ears.	
Headache	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 19/05/2004 **Stopped:** 28/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/06/2004	Other data				

Additional Information:

Patient was also taking Tegretol, Tenormin, Karvea, cartia, Serepax.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197923 **Seq:** 1
Reported: 07/06/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 25
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Serotonin syndrome.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197929 **Seq:** 1
Reported: 07/06/2004
Hospitalisation: Admitted to hospital
Onset Date: 13/05/2004
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 19
DOB: 13/02/1985
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Meningitis	Caused or prolonged inpatient hospitalisation	meningitis, respiratory arrest, disorientation, mood swings and cognitive impairment	
Cognitive disorder	Caused or prolonged inpatient hospitalisation		
Disorientation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** 13/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Budesonide and Salbutamol.
Respiratory arrest in the ambulance on the way to the hospital.
Comments: Long latency.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 197929 **Seq:** 1
Reported: 07/06/2004
Hospitalisation: Admitted to hospital
Onset Date: 13/05/2004
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 19
DOB: 13/02/1985
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mood swings	Caused or prolonged inpatient hospitalisation		
Respiratory arrest	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** 13/05/2004

Laboratory Investigations:

Additional Information:

Patient was also taking Budesonide and Salbutamol.
Respiratory arrest in the ambulance on the way to the hospital.
Comments: Long latency.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198102 **Seq:** 1 **Gender:** M
Reported: 11/06/2004 **Weight:** 90.00
Hospitalisation: **Age:** 38
Onset Date: 31/05/2004 **DOB:** 02/11/1965
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Completed suicide		Found hung 5 days after commencing	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 27/05/2004 **Stopped:** 31/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Hung himself 5 days after commencing Zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198174 **Seq:** 1 **Gender:** F
Reported: 16/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 29/03/2004 **DOB:** 06/06/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrooesophageal reflux diseas	Caused or prolonged inpatient hospitalisation	Oesophageal reflux, hiatus hernia, muscle weakness, nausea, vomiting, abdominal pain, scleroderma and creatine kinase high, abnormaL LFT's abnormal.	
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase in	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/06/2004	ALT = SGPT		31/03/2004	41	
16/06/2004	AST = SGOT		31/03/2004	61	
16/06/2004	AST = SGOT		10/05/2004	75	
16/06/2004	Albumin		10/05/2004	30	
16/06/2004	Creatine		31/03/2004	922	
16/06/2004	Creatine		10/05/2004	1000	
16/06/2004	LDH		31/03/2004	430	

Additional Information:

Patient was a particpant in clinical trial (unblinded) and treated with RAD001 for treatment of pulmonary fibrosis. Occurred during CT but not CT drug.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198174 **Seq:** 1 **Gender:** F
Reported: 16/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 29/03/2004 **DOB:** 06/06/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hiatus hernia	Caused or prolonged inpatient hospitalisation		
Liver function test abnormal	Caused or prolonged inpatient hospitalisation		
Muscular weakness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/06/2004	Other data				
16/06/2004	SAP = ALP		31/03/2004	128	

Additional Information:

Patient was a particpant in clinical trial (unblinded) and treated with RAD001 for treatment of pulmonary fibrosis. Occurred during CT but not CT drug.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198174 **Seq:** 1 **Gender:** F
Reported: 16/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: 29/03/2004 **DOB:** 06/06/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation		
Scleroderma	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

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

Laboratory Investigations:

Additional Information:

Patient was a particpant in clinical trial (unblinded) and treated with RAD001 for treatment of pulmonary fibrosis. Occurred during CT but not CT drug.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198306 **Seq:** 1 **Gender:** F
Reported: 21/06/2004 **Weight:** 56.00
Hospitalisation: **Age:** 26
Onset Date: **DOB:** 07/03/1978
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Visit to Doctor	Pruritis - severe and generalised and abnormal, liver function tests - cholestatic changes.	Questran 1/tds given.
Cholestasis	Required Visit to Doctor		
Liver function test abnormal	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 05/04/2004 **Stopped:** 15/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Gastroenterologist confermed drug reaction of Zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198329 **Seq:** 1
Reported: 21/06/2004
Hospitalisation: Required a visit to the doctor
Onset Date: 03/06/2004
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 22
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Life	Patient took 16 Zoloft 50mg tablets and tried to "end everything". He experienced some drowsiness and upset stomach	
Drug ineffective	Life		
Somnolence	Life		
Stomach discomfort	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 800.0 Milligram Daily Oral

Batch: **Started:** 03/06/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient receiving Zoloft 50mg daily for depression at the time he attempted to commit suicide. Dose increase to 100mg daily following counselling.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198349 **Seq:** 1 **Gender:** U
Reported: 21/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 72Y
Onset Date: 25/05/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Required Visit to Doctor	Tinnitus - ringing in ears.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 12/05/2004 **Stopped:** 31/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has noticed some improvement since ceasing medication. Also taking Norvasc, Lipitor, Zyloprim and Cartia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198558 **Seq:** 1 **Gender:** F
Reported: 28/06/2004 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 55Y
Onset Date: 06/04/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations	Treated in outpatient department only	Palpitations and numbness in hands and	Zoloft ceased.
Hypoaesthesia	Treated in outpatient department only		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of cataract extractions and lens implants (bilateral) and a history of hypertension. Other drugs taken are Coversyl and Prothiaden. Copy of telephone report sent to reporter by Dr Purcell.

Report Detail

Case Number: 198591 **Seq:** 1 **Gender:** F
Reported: 30/06/2004 **Weight:** 0.00
Hospitalisation: **Age:** 14Y
Onset Date: 15/06/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination	Required Visit to Doctor	Pre-existing pseudohallucinations, auditory and visual, increased.	Sertraline ceased, treated using Risperidone.

Medicine Details:

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

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198652 **Seq:** 1 **Gender:** F
Reported: 02/07/2004 **Weight:** 50.00
Hospitalisation: **Age:** 99u
Onset Date: 28/06/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Nausea, stomach discomfort and fatigue.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 28/06/2004 **Stopped:** 29/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198798 **Seq:** 1
Reported: 08/07/2004
Hospitalisation: Admitted to hospital
Onset Date: 13/05/2004
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 19
DOB: 13/02/1985
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Meningitis	Caused or prolonged inpatient hospitalisation	Suspected meningitis.	Patient was on an (unspecified) antiviral.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 13/05/2004 **Stopped:** 01/06/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/07/2004	Magnetic				MRI of the brain on 25 May 2004: "Normal".
08/07/2004	Other data				A cerebrospinal fluid (CSF) tap and no meningitis or viris was

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198862 **Seq:** 1 **Gender:** F
Reported: 12/07/2004 **Weight:** 66.00
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 15/12/1954
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vulvovaginal discomfort		Vulval soreness twice when Zoloft	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

?thrush after 2 weeks.
Reaction onset date: 2002.
Suspected drug positive rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 198869 **Seq:** 1 **Gender:** F
Reported: 12/07/2004 **Weight:** 60.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Decreased appetite Weight decreased		Appetite loss and weight loss.	Zoloft ceased - changed to Axit

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 03/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Asmol and Seretide.
198869 is seq 01 of 198918 seq 02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199092 **Seq:** 1 **Gender:** M
Reported: 16/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 83
Onset Date: 01/03/2002 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Aggression Agitation		Patient was agitated, excited and	Sertraline ceased.

Medicine Details:

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

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 27/02/2002 **Stopped:** 06/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient les aggressive. Agitation resolved after 3-4 days.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199278 **Seq:** 1
Reported: 21/07/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 85
DOB: 21/01/1919
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucinations, mixed	Caused or prolonged inpatient hospitalisation	Hallucinations, agitation and confusion aggravated, delusion and hyponatraemia.	Reminyl was discontinued and risperidone 1mg with an increase to 2mg was started for psychotic symptoms. Zoloft was ceased.
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Other drug) **Reason:**
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 26/05/2004 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
25.0 Milligram
Batch: **Started:** 17/05/2004 **Stopped:** 31/05/2004

REMINYL (Suspected) **Reason:** Unspecified psychosis
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 19/05/2004 **Stopped:** 31/05/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/07/2004	Computerised				
21/07/2004	Other data				

Additional Information:

Hyponatremia, considered possibly due to sertraline hcl.
Patient was discharged to an interim care facility, medications included risperidone 2mg and mirtazapine 45 mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199278 **Seq:** 1
Reported: 21/07/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 85
DOB: 21/01/1919
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation		
Cognitive disorder	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Other drug) **Reason:**
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 26/05/2004 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
25.0 Milligram
Batch: **Started:** 17/05/2004 **Stopped:** 31/05/2004

REMINYL (Suspected) **Reason:** Unspecified psychosis
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 19/05/2004 **Stopped:** 31/05/2004 0

Laboratory Investigations:

Additional Information:

Hyponatremia, considered possibly due to sertraline hcl.
Patient was discharged to an interim care facility, medications included risperidone 2mg and mirtazapine 45 mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199278 **Seq:** 1
Reported: 21/07/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 85
DOB: 21/01/1919
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delusion	Caused or prolonged inpatient hospitalisation		
Dementia	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Other drug) **Reason:**
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 26/05/2004 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
25.0 Milligram
Batch: **Started:** 17/05/2004 **Stopped:** 31/05/2004

REMINYL (Suspected) **Reason:** Unspecified psychosis
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 19/05/2004 **Stopped:** 31/05/2004 0

Laboratory Investigations:

Additional Information:

Hyponatremia, considered possibly due to sertraline hcl.
Patient was discharged to an interim care facility, medications included risperidone 2mg and mirtazapine 45 mg.

Report Detail

Case Number: 199278 **Seq:** 1
Reported: 21/07/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 85
DOB: 21/01/1919
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation		
Psychotic disorder	Caused or prolonged inpatient hospitalisation		
Skin disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Other drug) **Reason:**
Tablet 45.0 Milligram Daily Oral
Batch: **Started:** 26/05/2004 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
25.0 Milligram
Batch: **Started:** 17/05/2004 **Stopped:** 31/05/2004

REMINYL (Suspected) **Reason:** Unspecified psychosis
Tablet 8.0 Milligram Daily Oral
Batch: **Started:** 19/05/2004 **Stopped:** 31/05/2004 0

Laboratory Investigations:

Additional Information:

Hyponatremia, considered possibly due to sertraline hcl.
Patient was discharged to an interim care facility, medications included risperidone 2mg and mirtazapine 45 mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199408 **Seq:** 1
Reported: 26/07/2004
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 63.00
Age: 55
DOB: 06/04/1949
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth	Required Visit to Doctor	Dry mouth.	
Dental caries	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 01/01/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft taken for approx. 4 months. Reaction have persisted with subsequent delelopment dental caries

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199478 **Seq:** 1 **Gender:** M
Reported: 29/07/2004 **Weight:** 90.00
Hospitalisation: **Age:** 41
Onset Date: 13/07/2004 **DOB:** 21/10/1962
Outcome: Recovered 17/07/2004 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Night sweats	Severe	Severe drenching night sweats.	Zoloft ceased.
C-reactive protein increased	Severe		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 05/07/2004 **Stopped:** 16/07/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/07/2004	C-Reactive Protein		11/06/2004	18	
29/07/2004	C-Reactive Protein		28/06/2004	6	
29/07/2004	C-Reactive Protein		16/07/2004	83	

Additional Information:

Cert-Rechallenge: When the patient resumed Zoloft he began night sweats again but not as severely as before.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199501 **Seq:** 1 **Gender:** M
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 20/08/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Violent ideation Intentional self-injury		Violent thoughts and cut himself, intentional self harm.	

Medicine Details:

MIRTAZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

ZOLOFT (Suspected) **Reason:**
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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199502 **Seq:** 1 **Gender:** F
Reported: 30/07/2004 **Weight:** 0.00
Hospitalisation: **Age:** 42
Onset Date: 15/05/2004 **DOB:** 12/06/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Obsessive-compulsive disorder Suicidal ideation		Intensely, dangerously and obsessively	ECT.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

She became intensely, dangerously and obsessively suicidal.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 199838 **Seq:** 1
Reported: 10/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Chest pain.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200107 **Seq:** 1
Reported: 18/08/2004
Hospitalisation:
Onset Date: 13/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 51
DOB: 08/06/1953
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased tendency to bruise	Required Visit to Doctor	Patient developed bruising spontaneously.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 14/07/2004 **Stopped:** 16/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Normal coagulation studies, platelets.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200117 **Seq:** 1 **Gender:** F
Reported: 18/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 22/07/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury	Life	Parasuicide and self mutilation.	Ceased Zoloft and changed to Edronax.
Self mutilation	Life		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** 01/01/2004 **Stopped:** 06/06/2004

GABAPENTIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200126 **Seq:** 1
Reported: 18/08/2004
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
Chest pain	Caused or prolonged inpatient hospitalisation	Chest pain, abdominal pain and urinary	
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Urinary retention	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200177 **Seq:** 1 **Gender:** F
Reported: 20/08/2004 **Weight:** 62.00
Hospitalisation: **Age:** 24
Onset Date: 15/02/2001 **DOB:** 13/05/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anal inflammation	Required Visit to Doctor	Electric shock like pain around anal area, sudden pain made worse when walking felt like paper weights around anus, made worse sometimes if any faeces on skin. Excruciating pain and caused a lot of emotional distress, caused sensitivity to anal area.	Neurontin up to 2700mg.
Paraesthesia	Required Visit to Doctor		
Proctalgia	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Pain
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft was started in 2000 and stopped in 2004.
Took Neurontin to combat anal pain. Varied dose, and lessened Zoloft at this point, anus a lot better. Went off Neutrontin and increased Zoloft and pain made a lot worse.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200366 **Seq:** 1 **Gender:** M
Reported: 27/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 14/06/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures	Clopine and Sertraline ceased.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
Batch: **Started:** **Stopped:**

CLOPINE (Interaction) **Reason:** Schizophrenia
Tablet 400.0 Milligram Daily
Batch: **Started:** 21/04/2004 **Stopped:** 14/07/2004

PARACETAMOL (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200369 **Seq:** 1 **Gender:** F
Reported: 27/08/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		Patient has experienced a second	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200383 **Seq:** 1
Reported: 30/08/2004
Hospitalisation:
Onset Date: 18/08/2004
Outcome: Not yet recovered

Gender: F
Weight: 80.00
Age: 62
DOB: 04/03/1942
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria	Required Visit to Doctor	Patient developed an urticarial rash to	

Medicine Details:

RAMIPRIL (Other drug) **Reason:** Essential benign hypertension

5.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** 0

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 03/08/2004 **Stopped:** 19/08/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous rash or allergy. Patient HIV + CD4)500.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200599 **Seq:** 1
Reported: 07/09/2004
Hospitalisation:
Onset Date: 27/08/2004
Outcome: Recovered with sequelae

Gender: M
Weight: 0.00
Age: 26
DOB: 21/03/1978
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Patient was found with tonic-clonic seizures on the floor, biting through his top lip (mucosal surface only) and hitting the left side of his forehead on a skirting board.	Haloperidol was immediately ceased, following that, Sertraline was ceased. He was commenced on Diazepam 5mg and had his nightly Clozaril dose withheld. Clozaril continued as per usual the

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
As necessary
Batch: **Started:** **Stopped:** 27/08/2004

CLOZARIL (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 19/08/2004 **Stopped:** Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200783 **Seq:** 1
Reported: 13/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 28/06/2004
Outcome: Recovered

Gender: F
Weight: 60.00
Age: 14
DOB: 24/08/1989
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Patient experienced an increase in suicid	Required a visit to doctor. Ceased medication. Hospitalised for 24 hours

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 03/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took overdose of Panadol (8 tabs) and Panadeine Forte (4 tabs) on 03/07/04 at midnight. Paracetamol levels no toxic and LFT's normal. History: Dysthyuria 2 years, allergies to Fluvoxamine 50mg for 3 months ceased because of sedation (day time somnolence).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200787 **Seq:** 1
Reported: 13/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 07/09/2004
Outcome: Unknown

Gender: F
Weight: 47.00
Age: 31
DOB: 11/06/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced a seizure, dilated pupils, tremor and convulstion grand mal.	Monitard and CT performed.
Grand mal convulsion	Caused or prolonged inpatient hospitalisation		
Mydriasis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MOBIC (Other drug) **Reason:**
8.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

XANAX (Other drug) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 200787 **Seq:** 1
Reported: 13/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 07/09/2004
Outcome: Unknown

Gender: F
Weight: 47.00
Age: 31
DOB: 11/06/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MOBIC (Other drug) **Reason:**
8.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

XANAX (Other drug) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200948 **Seq:** 1 **Gender:** F
Reported: 20/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy Agitation neonatal Drug withdrawal syndrome neona Neonatal respiratory depression		jitteriness and respiratory depression thought to be due to maternal zoloft use	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Dose Unspecified 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 200958 **Seq:** 1 **Gender:** F
Reported: 20/09/2004 **Weight:** 56.00
Hospitalisation: **Age:** 49
Onset Date: 09/09/2004 **DOB:** 01/09/1955
Outcome: Recovered 12/09/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Required Visit to Doctor	Headache occitital and achey neck.	Withdrawal of Zoloft, changed to another SNRI, given Panadol
Neck pain	Required Visit to Doctor		

Medicine Details:

BLACK COHOSH (Other drug) **Reason:** Menopausal symptoms
3.0 Dose Unspecified Daily
Batch: **Started:** 04/09/2004 **Stopped:**

QVAR AUTOHALER (Other drug) **Reason:**
Inhalation 100.0 Microgram Daily Inhalation
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/09/2004 **Stopped:** 11/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201245 **Seq:** 1 **Gender:** F
Reported: 24/09/2004 **Weight:** 75.00
Hospitalisation: **Age:** 61
Onset Date: **DOB:** 19/04/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Required Visit to Doctor	The patient experienced sweating, shivering, dizziness, tremor, fever and was uncooordinated - Serotonin syndrome.	Zoloft ceased
Chills	Required Visit to Doctor		
Coordination abnormal	Required Visit to Doctor		
Dizziness	Required Visit to Doctor		
Pyrexia	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 10/03/2004 **Stopped:** 07/09/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to sulphur

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201245 **Seq:** 1 **Gender:** F
Reported: 24/09/2004 **Weight:** 75.00
Hospitalisation: **Age:** 61
Onset Date: **DOB:** 19/04/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Visit to Doctor		
Tremor	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 10/03/2004 **Stopped:** 07/09/2004 0

Laboratory Investigations:

Additional Information:
Allergic to sulphur

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201385 **Seq:** 1 **Gender:** M
Reported: 30/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 82Y
Onset Date: 11/08/2004 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		The patient developed hyponatraemia.	Sertraline meaned then

Medicine Details:

ALENDRONATE SODIUM (Other drug) **Reason:**
70.0 Milligram Weekly Oral
Batch: **Started:** L TERM **Stopped:**

SALBUTAMOL (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** L TERM **Stopped:**

ATROVENT (Other drug) **Reason:**
500.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

SEREVENT (Other drug) **Reason:**
56.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/09/2004	Creatinine		11/07/2004	0.094	
30/09/2004	Creatinine		11/08/2004	0.074	
30/09/2004	Potassium		11/07/2004	4.5	
30/09/2004	Serum osmolality	280 - 300	14/08/2004	273	
30/09/2004	Sodium		11/07/2004	128	
30/09/2004	Sodium		20/07/2004	128	
30/09/2004	Sodium		11/08/2004	125	

Additional Information:

Previous exposure to sertraline produced same reaction.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201385 **Seq:** 1 **Gender:** M
Reported: 30/09/2004 **Weight:** 0.00
Hospitalisation: **Age:** 82Y
Onset Date: 11/08/2004 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Medicine Details:

CHLORSIG (Other drug)				**Reason:**		
Eye Drops		8.0	Dose Unspecified	Daily		
Batch:	**Started:**		L TERM		**Stopped:**	
COLOXYL WITH SENNA (Other drug)				**Reason:**		
Tablet		4.0	Dose Unspecified	Daily		Oral
Batch:	**Started:**				**Stopped:**	
SERTRALINE HYDROCHLORIDE (Suspected)				**Reason:**		
Tablet		50.0	Milligram	Daily		Oral
Batch:	**Started:**	03/08/2004			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/09/2004	Sodium		13/08/2004	130	
30/09/2004	Sodium		17/08/2004	129	
30/09/2004	Sodium		18/08/2004	131	
30/09/2004	Sodium		19/08/2004	132	
30/09/2004	Sodium		20/08/2004	135	
30/09/2004	Sodium		22/08/2004	135	
30/09/2004	Urine osmolality	40 - 1400	14/08/2004	545	

Additional Information:

Previous exposure to sertraline produced same reaction.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201449 **Seq:** 1 **Gender:** F
Reported: 05/10/2004 **Weight:** 91.00
Hospitalisation: **Age:** 37
Onset Date: 29/09/2004 **DOB:** 31/01/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Coma Depression Drug ineffective		Patient developed Serotonin syndrome, comatose, depression..	

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Osteoarthritis
100.0 Milligram As necessary
Batch: **Started:** **Stopped:**

ZOLOFT (Interaction) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ENDONE (Interaction) **Reason:** Osteoarthritis
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:** Osteoarthritis
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 201449 **Seq:** 1 **Gender:** F
Reported: 05/10/2004 **Weight:** 91.00
Hospitalisation: **Age:** 37
Onset Date: 29/09/2004 **DOB:** 31/01/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201474 **Seq:** 1 **Gender:** M
Reported: 05/10/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 57
Onset Date: 26/09/2004 **DOB:** 26/12/1946
Outcome: Recovered 28/09/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Caused or prolonged inpatient hospitalisation	Patient experienced insomnia, somnolence, nightmares, anxiety and agitation	Zoloft ceased
Agitation	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMOXYCILLIN SODIUM (Other drug) **Reason:**
Capsule 250.0 Milligram Oral
Batch: **Started:** **Stopped:**

HIPREX (Other drug) **Reason:**
Tablet 1.0 Gram Oral
Batch: **Started:** **Stopped:**

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

ACCUPRIL (Other drug) **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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201474 **Seq:** 1 **Gender:** M
Reported: 05/10/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 57
Onset Date: 26/09/2004 **DOB:** 26/12/1946
Outcome: Recovered 28/09/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMADOL HYDROCHLORIDE (Other drug) **Reason:**
Capsule 50.0 Milligram Oral
Batch: **Started:** **Stopped:** 21/09/2004

ROCEPHIN (Other drug) **Reason:**
Injection 1.0 Gram
Batch: **Started:** **Stopped:**

CLOFEN (Other drug) **Reason:**
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Oral
Batch: **Started:** **Stopped:** 27/09/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201514 **Seq:** 1 **Gender:** F
Reported: 07/10/2004 **Weight:** 75.00
Hospitalisation: **Age:** 32
Onset Date: 16/09/2004 **DOB:** 08/03/1972
Outcome: Recovered 27/09/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Diarrhoea lasting 10 days.	Supportive.

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 16/09/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 201594 **Seq:** 1 **Gender:** U
Reported: 11/10/2004 **Weight:** 51.00
Hospitalisation: **Age:** 26
Onset Date: 30/09/2004 **DOB:** 15/06/1978
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor	Rash started on stomach and back then spread all over body and face.	Ceased Zoloft, treated with Dilosyn 4mg/tds/prn.

Medicine Details:

CAPADEX (Other drug) **Reason:** Pain
Capsule 8.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

ELEVIT RDI (Other drug) **Reason:** Unspecified anemia
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 22/09/2004 **Stopped:**

F.G.F. (Other drug) **Reason:** Unspecified anemia
1.0 Dose Unspecified Daily
Batch: **Started:** 22/09/2004 **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Oral
Batch: **Started:** 22/09/2004 **Stopped:** 01/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Developed 8 days after initiation of treatment with Zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202098 **Seq:** 1 **Gender:** F
Reported: 27/10/2004 **Weight:** 60.00
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 02/11/1964
Outcome: Recovered **Causality:** Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Required Visit to Doctor	Patient experienced urinary retention documented with high residual on ultrasound, urethral spasm and recurrent UTIs	
Bladder spasm	Required Visit to Doctor	Urethral spasm	
Urinary tract infection	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 01/04/2004 **Stopped:** 05/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is cert/rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202253 **Seq:** 1
Reported: 03/11/2004
Hospitalisation: Treated in Accident/Emergency Department
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 53.00
Age: 80
DOB: 25/09/1924
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Back pain Confusional state Dry mouth Dysarthria Serotonin syndrome		Confused, dry mouth, back pain, slurred speech, serotonin syndrome.	Tramadol ceased.

Medicine Details:

TRAMAL (Interaction)			**Reason:**	Otr&unsp vertebrogen pain synd	
Injection	50.0	Milligram	1 time		Intramuscular
Batch:	**Started:**	14/06/2004		**Stopped:**	
ZOLOFT (Interaction)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	0
TRAMAL (Interaction)			**Reason:**	Otr&unsp vertebrogen pain synd	
Capsule	100.0	Milligram	Daily		Oral
Batch:	**Started:**	14/06/2004		**Stopped:**	21/06/2004
ASTRIX 100 (Other drug)			**Reason:**	Other coagulation defects	
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:**	L TERM		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Main reason for confusion seems to be dementia and age. However, confusion documented to decrease after withdrawal of Tramadol.

Report Detail

Case Number: 202253 **Seq:** 1
Reported: 03/11/2004
Hospitalisation: Treated in Accident/Emergency Department
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 53.00
Age: 80
DOB: 25/09/1924
Causality: Causality possible

Reaction Detail

Medicine Details:

VASOCARDOL (Other drug)			**Reason:**	Essential benign hypertension	
Capsule	240.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	
TRITACE (Other drug)			**Reason:**	Essential benign hypertension	
	10.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	
MONODUR (Other drug)			**Reason:**	Angina pectoris w/o hyperten	
Tablet	60.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	
ACIMAX (Other drug)			**Reason:**	Other diseases of esophagus	
Tablet	20.0	Milligram	Daily	Oral	
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:

Main reason for confusion seems to be dementia and age. However, confusion documented to decrease after withdrawal of Tramadol.

Report Detail

Case Number: 202253 **Seq:** 1
Reported: 03/11/2004
Hospitalisation: Treated in Accident/Emergency Department
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 53.00
Age: 80
DOB: 25/09/1924
Causality: Causality possible

Reaction Detail

Medicine Details:

PANADOL (Other drug)			**Reason:**	Pain	
	4.0	Gram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
TEMAZEPAM (Other drug)			**Reason:**	Specific disorders of sleep	
	10.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	
Novomix 30 (Other drug)			**Reason:**	Diabetes mellitus	
Tablet	30.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:

Main reason for confusion seems to be dementia and age. However, confusion documented to decrease after withdrawal of Tramadol.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202315 **Seq:** 1 **Gender:** M
Reported: 04/11/2004 **Weight:** 57.00
Hospitalisation: Admitted to hospital **Age:** 17
Onset Date: 23/10/2004 **DOB:** 29/11/1986
Outcome: Recovered 27/10/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	Family reported increased suicidality and self-harming behaviours.	Hospitalisation

Medicine Details:

MIRTAZAPINE (Other drug) **Reason:** Depression
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 01/10/2004 **Stopped:** 23/10/2004

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 01/10/2004 **Stopped:** 24/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred three weeks after Sertraline was increaed from 50mg to 75mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202357 **Seq:** 1 **Gender:** M
Reported: 08/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: 15/09/2002 **DOB:** 08/04/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary hesitation	Required Visit to Doctor	Hesitancy of urination on terminal dribble.	Zoloft dose reduced
Urinary incontinence	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 02/09/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Brother has similar symptoms on another SSRI.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202534 **Seq:** 1 **Gender:** M
Reported: 15/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 50Y
Onset Date: 20/10/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression	Required Visit to Doctor	Within a week of starting Zoloft patient developed deep depression, suicidal tendencies	Saw Psychiatrist who withdrew Zoloft
Suicidal ideation	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 15/10/2002 **Stopped:** 30/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202561 **Seq:** 1 **Gender:** F
Reported: 15/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 21/01/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Required Visit to Doctor	The patient suffered anxiety and panic attacks. She was commenced on Zoloft and the anxiety became worse.	Zoloft ceased, Xanax
Anxiety	Required Visit to Doctor		
Panic attack	Required Visit to Doctor		

Medicine Details:

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

Tablet 1.0 Dose Unspecified Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Long reaction with psychotic disability. Currently on Xanax.

Report Detail

Case Number: 202651 **Seq:** 1 **Gender:** F
Reported: 18/11/2004 **Weight:** 60.00
Hospitalisation: **Age:** 17
Onset Date: 11/11/2004 **DOB:** 05/03/1987
Outcome: Recovered 11/11/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Required Visit to Doctor	Faint/loss of consciousness for 5 minutes after 4 minute walk.	
Loss of consciousness	Required Visit to Doctor		

Medicine Details:

IRON (Other drug) **Reason:** Unspecified anemia
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 10/11/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of anaemia and 1 faint 2 yesr ago secondary to anaemia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202683 **Seq:** 1 **Gender:** F
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: **DOB:** 19/02/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation Akathisia Personality change Suicidal ideation		Patient suffered akathisia, suicidal ideation, personality change and homicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

EFEXOR (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202684 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 12/06/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202686 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 11/08/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Felt suicidal after 4 doses of Zoloft.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202699 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: **DOB:** 20/11/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Overdose Serotonin syndrome		Patient overdosed on Efexor and Zoloft and had Serotonergic syndrome.	Discharged on Olanzapine.

Medicine Details:

EFEXOR (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202707 **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
Homicidal ideation Aggression Agitation Delusion		Homicidal ideation, delusions, agitation and aggression.	Discharged on Sertraline and Olanzapine.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202710 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 02/04/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Overdose		Overdose on Zoloft and alcohol.	Discharged on Zoloft 100mg.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
Oral Liquid 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202719 **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		Suicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 200.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202720 **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 Aggression		Suicidal ideation and violent.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202730 **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		Suicidal ideation.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected) **Reason:**
Injection 20.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZYPREXA (Suspected) **Reason:**
9.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202778 **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 Aggression		Suicidal ideation and violence.	

Medicine Details:

RISPERDAL (Suspected) **Reason:**
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 202780 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: **DOB:** 08/10/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Patient became abusive.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

OLANZAPINE (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZUCLOPENTHIXOL ACETATE (Suspected) **Reason:**
Injection
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202785 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: **DOB:** 26/12/1979
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 200.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202788 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 28/02/2003 **DOB:** 11/05/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 150.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202790 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 07/10/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 300.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202793 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 01/03/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202797 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 06/02/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Patient became violent and psychotic.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202798 **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
Overdose		Patient overdosed.	

Medicine Details:

EFEXOR (Suspected) **Reason:**
Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202807 **Seq:** 1 **Gender:** U
Reported: 18/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 13/06/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Akathisia Suicide attempt		Suicidal ideation, 2 suicide attempts and six weeks of akathisia.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202831 **Seq:** 1 **Gender:** F
Reported: 19/11/2004 **Weight:** 60.00
Hospitalisation: **Age:** 75
Onset Date: 10/05/2004 **DOB:** 16/07/1928
Outcome: Death, maybe drug 10/05/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Drug ineffective, depression, suicide - Carbon Monoxide toxicity.	
Dyspepsia		Indigestion, knots in stomach, upset stomache, difficulty sleeping, dry mouth, decreased appetite	
Visual disturbance		Visual disturbances and blurred vision, shaking, tremors (unable to hold a glass of water without spilling it).	
Completed suicide			
Decreased appetite			
Drug ineffective			
Dry mouth			
Insomnia			

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 did not start it until 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. Patient finally connected a hose to the exhaust of her car and died of carbon monoxide poisoning. Suicide was Carbon Monoxide Toxicity. Coroner's report - 87% of haemoglobulin in the form of carboxyhaemoglobulin. A low therapeutic level of Sertraline. "Incised wounds of the wrists", had not caused significant haemorrhage.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202831 **Seq:** 1 **Gender:** F
Reported: 19/11/2004 **Weight:** 60.00
Hospitalisation: **Age:** 75
Onset Date: 10/05/2004 **DOB:** 16/07/1928
Outcome: Death, maybe drug 10/05/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Vision blurred			

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:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 03/05/2004 **Stopped:** 09/05/2004 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 did not start it until 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. Patient finally connected a hose to the exhaust of her car and died of carbon monoxide poisoning. Suicide was Carbon Monoxide Toxicity. Coroner's report - 87% of haemoglobulin in the form of carboxyhaemoglobulin. A low therapeutic level of Sertraline. "Incised wounds of the wrists", had not caused significant haemorrhage.

Report Detail

Case Number: 202846 **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
Suicidal ideation Homicidal ideation		Suicidal and homicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
Oral Liquid Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took Zoloft irregularly.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202850 **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 at home.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202867 **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
Akathisia Suicide attempt		Akathisia, suicidal ideation and suicide attempt	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202868 **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
Suicidal ideation		Suicidal ideation.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202915 **Seq:** 1
Reported: 22/11/2004
Hospitalisation:
Onset Date: 08/11/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 61
DOB: 17/02/1943
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Visit to Doctor	Noticed itching, rash appeared. Hands swollen - itchy; worse where perspiration on (groin, wrists and trunk).	Corticosteroid cream given.
Oedema peripheral	Required Visit to Doctor		
Rash	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 26/10/2004 **Stopped:** 09/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to Lipitor approximately years ago.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202967 **Seq:** 1 **Gender:** F
Reported: 23/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Self injurious behaviour		Suicidal ideation, self injurious behavior.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202989 **Seq:** 1 **Gender:** F
Reported: 23/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Drug exposure during pregnancy Hyperglycaemia		The child had breathing problems and hyperglycaemia after delivery.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: Diabetic.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 202995 **Seq:** 1 **Gender:** F
Reported: 23/11/2004 **Weight:** 29.00
Hospitalisation: **Age:** 39
Onset Date: 15/04/1999 **DOB:** 21/01/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Required Visit to Doctor	Intense anxiety, unable to sleep, felt	Zoloft ceased.
Insomnia	Required Visit to Doctor		
Suicidal ideation	Required Visit to Doctor		

Medicine Details:

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203128 **Seq:** 1 **Gender:** M
Reported: 30/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Life	Kept him awake all night all night, experienced suicidal ideation, "planned to jump off a bridge"	Ceased Zoloft.
Suicidal ideation	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203144 **Seq:** 1 **Gender:** F
Reported: 30/11/2004 **Weight:** 117.00
Hospitalisation: **Age:** 36Y
Onset Date: 15/04/2004 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Treated in outpatient department only	The patient experienced nausea, vomiting, tachycardia, tremor, was agitated, dizzy, had trouble breathing with swelling or closing of the throat and was sweating. Two weeks later the patient took half a tablet with the same effect, except no vomiting. She went to the emergency ward and was kept for 5-7 hours before being	Heart monitored, Diazepam 2mg and Aspirin. Zoloft ceased
Agitation	Treated in outpatient department only		
Dizziness	Treated in outpatient department only		

Medicine Details:

MICROGYNON 50 (Other drug) **Reason:** Contraception

Tablet 1.0 Dose Unspecified Daily Oral

Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

2 weeks later took 1/2 a tablet with same effect except no vomiting - and went to emergency ward lept for 5-7hrs before discharged.
Suspect drug positive rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203144 **Seq:** 1 **Gender:** F
Reported: 30/11/2004 **Weight:** 117.00
Hospitalisation: **Age:** 36Y
Onset Date: 15/04/2004 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Treated in outpatient department only		
Pharyngeal oedema	Treated in outpatient department only		
Tachycardia	Treated in outpatient department only		
Tremor	Treated in outpatient department only		

Medicine Details:

MICROGYNON 50 (Other drug) **Reason:** Contraception

Tablet 1.0 Dose Unspecified Daily Oral

Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

2 weeks later took 1/2 a tablet with same effect except no vomiting - and went to emergency ward lept for 5-7hrs before discharged.
Suspect drug positive rechallenge.

Report Detail

Case Number: 203144 **Seq:** 1 **Gender:** F
Reported: 30/11/2004 **Weight:** 117.00
Hospitalisation: **Age:** 36Y
Onset Date: 15/04/2004 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Treated in outpatient department only		

Medicine Details:

MICROGYNON 50 (Other drug) **Reason:** Contraception

Tablet 1.0 Dose Unspecified Daily Oral

Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram 1 time Oral

Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

2 weeks later took 1/2 a tablet with same effect except no vomiting - and went to emergency ward lept for 5-7hrs before discharged.
Suspect drug positive rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203148 **Seq:** 1 **Gender:** M
Reported: 30/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 14Y
Onset Date: 15/10/2003 **DOB:**
Outcome: Recovered 15/11/2003 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Required Visit to Doctor	When the dosage of Zoloft was increased the child had a manic reaction.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 15/01/2003 **Stopped:** 15/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203165 **Seq:** 1 **Gender:** M
Reported: 01/12/2004 **Weight:** 47.00
Hospitalisation: **Age:** 76
Onset Date: 15/11/2004 **DOB:** 26/12/1927
Outcome: Recovered 19/11/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropaenia.	

Medicine Details:

MIRTAZAPINE (Other drug) **Reason:**
15.0 Milligram
Batch: **Started:** 04/11/2004 **Stopped:**

RULIDE (Other drug) **Reason:**
300.0 Milligram
Batch: **Started:** 25/10/2004 **Stopped:**

CLINDAMYCIN HYDROCHLORIDE (Other drug) **Reason:**
1.0 Gram
Batch: **Started:** 25/10/2004 **Stopped:**

ASPIRIN (Other drug) **Reason:**
100.0 Milligram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203165 **Seq:** 1 **Gender:** M
Reported: 01/12/2004 **Weight:** 47.00
Hospitalisation: **Age:** 76
Onset Date: 15/11/2004 **DOB:** 26/12/1927
Outcome: Recovered 19/11/2004 **Causality:** Causality probable

Reaction Detail

Medicine Details:

PERINDOPRIL (Other drug)		**Reason:**	
	4.0 Milligram		
Batch:	**Started:**		**Stopped:**
PRAVASTATIN SODIUM (Other drug)		**Reason:**	
	40.0 Milligram		
Batch:	**Started:**		**Stopped:**
DIGOXIN (Other drug)		**Reason:**	
	62.0 Microgram		
Batch:	**Started:**		**Stopped:**
COLCHICINE (Other drug)		**Reason:**	
	1.0 Milligram		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203165 **Seq:** 1 **Gender:** M
Reported: 01/12/2004 **Weight:** 47.00
Hospitalisation: **Age:** 76
Onset Date: 15/11/2004 **DOB:** 26/12/1927
Outcome: Recovered 19/11/2004 **Causality:** Causality probable

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet	50.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 04/11/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

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:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203256 **Seq:** 1 **Gender:** M
Reported: 03/12/2004 **Weight:** 70.00
Hospitalisation: **Age:** 17
Onset Date: 25/11/2004 **DOB:** 05/10/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Calculus bladder	Required Visit to Doctor	Patient developed ureteric calculus.	

Medicine Details:

Augmentin Duo (Suspected) **Reason:** Othr diseases of urinary tract
2.0 Dose Unspecified Daily Oral
Batch: **Started:** 20/11/2004 **Stopped:** 25/11/2004

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/12/2004	Urate				Normal Caltrate, cyctine and urate.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203272 **Seq:** 1 **Gender:** F
Reported: 06/12/2004 **Weight:** 0.00
Hospitalisation: **Age:** 94
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Amnesia Anorexia Cognitive disorder		Patient described as a "zombie", "drugged out", glassy eyed, disinterested, has memory lost, congnitive function decreased and lost her appetite	

Medicine Details:

SEREPAX (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203284 **Seq:** 1 **Gender:** M
Reported: 06/12/2004 **Weight:** 74.00
Hospitalisation: **Age:** 83
Onset Date: 24/11/2004 **DOB:** 07/06/1921
Outcome: Recovered 30/11/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema	Required Visit to Doctor	Patient developed angio-oedema, penile oedema, abnormal liver function test and sore throat.	Zoloft ceased 26/11/2004.
Liver function test abnormal	Required Visit to Doctor		
Pharyngolaryngeal pain	Required Visit to Doctor		

Medicine Details:

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PREDNISOLONE (Other drug) **Reason:** Otr mus rheum,fibrosit&myalgia
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

TEMAZE (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

NOTEN (Other drug) **Reason:** Chron isch heart dis no hyper
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 23/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had Zoloft in 1999 for same condition - no problems then. Also allergic to Celebrex and Doxycycline.

Report Detail

Case Number: 203284 **Seq:** 1 **Gender:** M
Reported: 06/12/2004 **Weight:** 74.00
Hospitalisation: **Age:** 83
Onset Date: 24/11/2004 **DOB:** 07/06/1921
Outcome: Recovered 30/11/2004 **Causality:** Causality probable

Reaction Detai

Medicine Details:

VOLTAREN (Other drug)			**Reason:**	Osteoarthritis	
	100.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	23/11/2004
ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	100.0	Milligram	Daily	Oral	
Batch:	**Started:**	08/08/2004		**Stopped:**	26/11/2004 0

Laboratory Investigations:

Additional Information:

Patient had Zoloft in 1999 for same condition - no problems then. Also allergic to Celebrex and Doxycycline.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203326 **Seq:** 1 **Gender:** F
Reported: 07/12/2004 **Weight:** 55.00
Hospitalisation: **Age:** 62
Onset Date: 11/11/2004 **DOB:** 25/04/1942
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Muscle spasms Vasodilatation			

Medicine Details:

LIVIAL (Other drug) **Reason:** Menopausal symptoms
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 11/10/2004 **Stopped:** 11/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203412 **Seq:** 1
Reported: 10/12/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 52.00
Age: 16
DOB: 25/03/1988
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness Epilepsy		Loss of consciousness and epilepsy.	Zoloft therapy was

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anorexia
Tablet 100.0 Milligram Oral
Batch: **Started:** 01/04/2004 **Stopped:** 31/12/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203414 **Seq:** 1 **Gender:** F
Reported: 10/12/2004 **Weight:** 60.00
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 08/07/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting Anxiety Diarrhoea Flushing Hyperhidrosis Nausea Serotonin syndrome Vein disorder		Experienced vomiting, nausea, flushing, diarrhoea, sweating, anxiety, veins standing out and serotonin syndrome.	

Medicine Details:

EUGYNON (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LEVONORGESTREL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram 1 time 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203417 **Seq:** 1 **Gender:** F
Reported: 10/12/2004 **Weight:** 55.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 01/05/1969
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Sleep disorder		Experienced debilitating sweating, the patient was waking at night and having to change sheets	Zoloft was ceased.

Medicine Details:

PANADEINE (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:**

CELECOXIB (Other drug) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 23/04/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203613 **Seq:** 1 **Gender:** F
Reported: 16/12/2004 **Weight:** 56.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 20/02/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Required Specialist Consultation	Patient deteriorated again with sweats, tremor, some clouding of mental state, nausea and anorexia	Zoloft ceased. Edronax 4mg
Anorexia	Required Specialist Consultation		
Mental disorder	Required Specialist Consultation		
Nausea	Required Specialist Consultation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 02/09/2004 **Stopped:** 21/09/2004

BUPRENORPHINE HYDROCHLORIDE (Suspected) **Reason:**
12.0 Milligram Alternate days
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 203613 **Seq:** 1 **Gender:** F
Reported: 16/12/2004 **Weight:** 56.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 20/02/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Required Specialist Consultation		
Tremor	Required Specialist Consultation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 02/09/2004 **Stopped:** 21/09/2004

BUPRENORPHINE HYDROCHLORIDE (Suspected) **Reason:**
12.0 Milligram Alternate days
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203617 **Seq:** 1
Reported: 17/12/2004
Hospitalisation:
Onset Date: 01/11/2004
Outcome: Not yet recovered

Gender: M
Weight: 75.00
Age: 51
DOB: 20/10/1953
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus		Gradual onset of tinnitus.	No treatment given.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 20/10/2004 **Stopped:** 08/12/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms cleared in 48 hours after ceasation. Returned but at much lower intensity on resuming zoloft at 1/2 dose.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203633 **Seq:** 1 **Gender:** F
Reported: 17/12/2004 **Weight:** 72.00
Hospitalisation: **Age:** 34
Onset Date: 24/10/2004 **DOB:** 16/12/1969
Outcome: Recovered 08/12/2004 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis allergic	Required Visit to Doctor	Patient experienced a severe allergic	Ceased Zoloft.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 25/08/2004 **Stopped:** 25/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203702 **Seq:** 1 **Gender:** M
Reported: 21/12/2004 **Weight:** 80.00
Hospitalisation: **Age:** 42
Onset Date: 13/11/2004 **DOB:** 20/12/1961
Outcome: Recovered 08/12/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal behaviour	Life	Uncharacteristically left his home in the early hours of the morning, went to another building, sat in bath holding gun to his chin, thinking of death as "a way out". Had been feeling agitated and paranoid.	Olanzapine 10mg nocte.
Agitation	Life		
Paranoia	Life		
Suicidal ideation	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 10/11/2004 **Stopped:** 13/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had similar period of agitation and paranoid ideation following abrupt cessation of reductil about 3 years earlier.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203813 **Seq:** 1 **Gender:** F
Reported: 23/12/2004 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsion.	

Medicine Details:

EPILIM (Other drug) **Reason:**
1.0 Gram
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of epilepsy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203846 **Seq:** 1 **Gender:** M
Reported: 17/12/2004 **Weight:** 80.00
Hospitalisation: **Age:** 63
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Required Specialist Consultation	The patient experienced agitation and worsening of OCD symptoms.	Xanax dose was increased, he was seeing a psychiatrist and was changed to Lexapro. Zoloft was ceased.
Drug ineffective	Required Specialist Consultation		

Medicine Details:

XANAX (Other drug) **Reason:** Anxiety neurosis
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 15/08/2004 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203876 **Seq:** 1 **Gender:** M
Reported: 04/01/2005 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 81
Onset Date: 19/11/2004 **DOB:** 09/10/1923
Outcome: Recovered 09/12/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mental impairment	Caused or prolonged inpatient hospitalisation	Moxifloxacin commenced 13/11/04 (400mg daily) patient's mental state deteriorated severely around 19/11, Moxafloxacin ceased 21/11/04. Patient lucid and able to communicate 23/11/04, agitated /lip smacking/repetitive action.	Moxafloxacin ceased.
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATROVENT (Other drug) **Reason:**
Batch: **Started:** 08/11/2004 **Stopped:** 11/12/2004

AMIODARONE HYDROCHLORIDE (Other drug) **Reason:** Otr&nos disord of heart rhythm
900.0 Milligram Daily
Batch: **Started:** 13/11/2004 **Stopped:** 17/11/2004

MOXIFLOXACIN (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 13/11/2004 **Stopped:** 21/11/2004 0

FLUCLOXACILLIN SODIUM (Suspected) **Reason:** Pneumonia,unspecified
4.0 Gram Daily
Batch: **Started:** 13/11/2004 **Stopped:** 22/11/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 203876 **Seq:** 1 **Gender:** M
Reported: 04/01/2005 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 81
Onset Date: 19/11/2004 **DOB:** 09/10/1923
Outcome: Recovered 09/12/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation		
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Incoherent	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUCONAZOLE (Suspected) **Reason:** Pneumonia,unspecified
400.0 Milligram Daily
Batch: **Started:** 15/11/2004 **Stopped:** 21/11/2004

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 09/11/2004 **Stopped:** 21/11/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204059 **Seq:** 1 **Gender:** M
Reported: 10/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 31/08/2004 **DOB:** 11/10/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Required Visit to Doctor	The patient experienced a pulmonary embolus, cardiomyopathy, moderately dilated left ventricle and Clozapine levels of 325ng/ml	Commenced Warfarin.
Cardiomyopathy	Required Visit to Doctor		
Dilatation ventricular	Required Visit to Doctor		
Drug level decreased	Required Visit to Doctor		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 14/07/2004 S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/01/2005	Echocardiogram				20/09/2004 Moderately dilated left ventricle.
10/01/2005	Serum drug level				22/11/2004 Clozapine levels 325ng/ml

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204150 **Seq:** 1 **Gender:** M
Reported: 12/01/2005 **Weight:** 95.00
Hospitalisation: Admitted to hospital **Age:** 59
Onset Date: **DOB:** 17/04/1945
Outcome: Recovered 10/10/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Migraine	Caused or prolonged inpatient hospitalisation	The patient developed a very severe intractable migraine headache one week after abrupt cessation of Zoloft.	
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVAPRO (Other drug) **Reason:** Essential benign hypertension
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

MINAX (Other drug) **Reason:** Chron isch heart dis no hyper
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PRAVACHOL (Other drug) **Reason:** Chron isch heart dis no hyper
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

PLAVIX (Other drug) **Reason:** Chron isch heart dis no hyper
Tablet 75.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204150 **Seq:** 1 **Gender:** M
Reported: 12/01/2005 **Weight:** 95.00
Hospitalisation: Admitted to hospital **Age:** 59
Onset Date: **DOB:** 17/04/1945
Outcome: Recovered 10/10/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204159 **Seq:** 1
Reported: 12/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 01/12/2004
Outcome: Recovered

Gender: F
Weight: 50.00
Age: 69
DOB: 25/06/1935
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue	Caused or prolonged inpatient hospitalisation	The patient experienced fatigue, dry retching, nausea, vomiting and felt like collapsing	Withhold Tramal, withhold Zoloft - recommended.
Nausea	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMAL (Interaction) **Reason:** Pain
150.0 Milligram Daily
Batch: **Started:** 01/12/2004 **Stopped:** 01/12/2004

ZOLOFT (Interaction) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SOLONE (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

XANAX (Other drug) **Reason:** Anxiety neurosis
Tablet 2.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204159 **Seq:** 1
Reported: 12/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 01/12/2004
Outcome: Recovered

Gender: F
Weight: 50.00
Age: 69
DOB: 25/06/1935
Causality: Causality possible

Reaction Detail

Medicine Details:

KARVEA (Other drug) **Reason:** Essential benign hypertension

Tablet 150.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204243 **Seq:** 1
Reported: 14/01/2005
Hospitalisation:
Onset Date: 15/10/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 28
DOB: 01/09/1976
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia	Required Specialist Consultation	The patient lost all body hair about one month after she started Zoloft.	

Medicine Details:

MONOFEME 28 (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** 01/09/2004 **Stopped:** 16/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

2/4/2005 - the alopecia continues.
patient has never taken zoloft before.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204285 **Seq:** 1 **Gender:** F
Reported: 17/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: 15/08/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, visual		Experienced visual hallucinations "funny" images amusing. Not frightening or	

Medicine Details:

METHADONE HYDROCHLORIDE (Suspected) **Reason:**
Oral Liquid, Syrup
Batch: **Started:** L TERM **Stopped:**

STILNOX (Suspected) **Reason:** Specific disorders of sleep
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** Continuing.

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 15/08/2004 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204292 **Seq:** 1 **Gender:** F
Reported: 17/01/2005 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 01/12/2004 **DOB:** 04/03/1968
Outcome: Recovered 24/12/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania	Caused or prolonged inpatient hospitalisation	Patient became elevated, erratic and abusive, required to be brought in to hospital by the police	Sodium Valproate 1000mg bd.
Aggression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 16/11/2004 **Stopped:** 11/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had 2 episodes of mania approx 10 years ago and a diagnosis of Bipolar Affective Disorder, but has been well since then and on no medications.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204549 **Seq:** 1 **Gender:** F
Reported: 24/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 06/12/2004 **DOB:** 02/07/1934
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon Hyponatraemia		The patient experienced SIADH and	Sertraline ceased, 3% Sodium Chloride given @ 50ml/h for 1.5 hours, then normal Saline infused @ 80ml/h.

Medicine Details:

STEMETIL (Other drug) **Reason:**
As necessary
Batch: **Started:** L TERM **Stopped:**

DIAZEPAM (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2005	Serum osmolality		06/12/2004	230	
24/01/2005	Sodium		02/09/2003	141	
24/01/2005	Sodium		06/12/2004	108	
24/01/2005	Sodium		07/12/2004	121	
24/01/2005	Sodium		13/12/2004	132	
24/01/2005	Sodium		09/12/2004	128	
24/01/2005	Urine Potassium		06/12/2004	53	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204549 **Seq:** 1 **Gender:** F
Reported: 24/01/2005 **Weight:** 0.00
Hospitalisation: **Age:** 70
Onset Date: 06/12/2004 **DOB:** 02/07/1934
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

STEMETIL (Other drug)			**Reason:**		
			As necessary		
Batch:	**Started:**		L TERM	**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**		
	10.0	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Tablet	150.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2005	Urine Sodium		06/12/2004	115	
24/01/2005	Urine osmolality		06/12/2004	423	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204977 **Seq:** 1 **Gender:** M
Reported: 05/02/2005 **Weight:** 64.00
Hospitalisation: **Age:** 72
Onset Date: 02/01/2005 **DOB:** 20/12/1932
Outcome: Recovered 17/01/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Required Visit to Doctor	Nausea, light headed when on full dose of Sertraline minor symptoms when on 25mg.	
Dizziness	Required Visit to Doctor		

Medicine Details:

FELODUR ER (Other drug) **Reason:** Essential benign hypertension
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ACCURETIC (Other drug) **Reason:** Essential benign hypertension
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

ASPIRIN (Other drug) **Reason:** Other coagulation defects
100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZANTAC (Other drug) **Reason:** Other diseases of esophagus
Tablet 300.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 204977 **Seq:** 1 **Gender:** M
Reported: 05/02/2005 **Weight:** 64.00
Hospitalisation: **Age:** 72
Onset Date: 02/01/2005 **DOB:** 20/12/1932
Outcome: Recovered 17/01/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

LIPITOR (Other drug)			**Reason:**	Othr&unspec metabolic diseases	
Tablet	10.0	Milligram	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Anxiety neurosis	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	**Started:**	16/12/2004	**Stopped:**	14/01/2005	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205271 **Seq:** 1 **Gender:** F
Reported: 14/02/2005 **Weight:** 96.00
Hospitalisation: **Age:** 54
Onset Date: 26/01/2005 **DOB:** 17/01/1951
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mood swings Anger Depression Drug therapy changed Headache		No positive effect of medication, increasing moodiness, headache, depression, negativity, anger.	Ceased Xydep, swapped back to Zoloft.

Medicine Details:

Xydep (Suspected) **Reason:** Othr disorders of menstruation

Tablet 0.0 Dose Unspecified Daily Oral

Batch: **Started:** 23/01/2005 **Stopped:** 01/02/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No history of headaches.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205272 **Seq:** 1 **Gender:** U
Reported: 15/02/2005 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 17/01/1953
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed		Changed from Zoloft to Xydep	
Nausea		Nausea 10 minutes after taking Xydep	Back to original prescription.

Medicine Details:

PERIACTIN (Other drug) **Reason:**
40.0 Milligram
Batch: **Started:** **Stopped:**

Xydep (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 03/02/2005 **Stopped:** 04/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug timing certain.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205292 **Seq:** 1
Reported: 16/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 15/09/2004
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 70Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Atrioventricular block	Caused or prolonged inpatient hospitalisation	Heart block, ventricular tachycardial,	Zoloft was ceased.
Depression	Caused or prolonged inpatient hospitalisation		
Drug ineffective	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Unspecified neurosis

Batch: **Started:** 01/09/2004 **Stopped:** 30/09/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient received many other medications, detail not provided.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205292 **Seq:** 1
Reported: 16/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 15/09/2004
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 70Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ventricular tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Unspecified neurosis

Batch: **Started:** 01/09/2004 **Stopped:** 30/09/2004 0

Laboratory Investigations:

Additional Information:

The patient received many other medications, detail not provided.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205331 **Seq:** 1
Reported: 16/02/2005
Hospitalisation:
Onset Date: 08/02/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 84
DOB: 15/11/1920
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		hyponatraemia	drug ceased slow Na prscribed 11/02/2005

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 100.0 Milligram 1 time Oral

Batch: unknown **Started:** 24/01/2005 **Stopped:** 10/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/02/2005	Sodium				Na levels: 18/01/05 125; 08/02/05 123; 10/02/05 122; 11/02/05 125; 12/02/05 128; 13/02/05 127; 14/02/05 129.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205441 **Seq:** 1 **Gender:** F
Reported: 22/02/2005 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 15/02/2005 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychomotor hyperactivity Anorexia Irritability Restlessness		The child of the patient, who was breast feeding, became hyperactive during the night, and during the day was irritable, restless and not feeding properly. This stopped when breast feeding stopped.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 15/01/2005 **Stopped:** 15/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was very compliant with 8 hour break before feeding but baby still experienced side effects.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205443 **Seq:** 1 **Gender:** F
Reported: 22/02/2005 **Weight:** 0.00
Hospitalisation: **Age:** 42Y
Onset Date: 31/01/2005 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Drug therapy changed Nausea Tension headache		The patient complained of 'pulsating' nerve, headache, nausea and tightness around the head after two days of taking Xydep 25 instead of Zoloft brand Sertraline.	

Medicine Details:

Xydep (Suspected) **Reason:**

Tablet 25.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Xydep given instead of Zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205486 **Seq:** 1 **Gender:** F
Reported: 23/02/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		The elderly patient developed symptoms of Syndrome of Inappropriate Anit-Diuretic Hormone secretion.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 17/01/2005 **Stopped:** 26/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205520 **Seq:** 1
Reported: 24/02/2005
Hospitalisation:
Onset Date: 08/02/2005
Outcome: Not yet recovered

Gender: F
Weight: 50.00
Age: 16
DOB: 16/03/1988
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	The patient attempted suicide by taking a Paracetamol overdose ten days after commencing Sertraline.	

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 31/01/2005 **Stopped:** 08/02/2005

SODIUM VALPROATE (Suspected) **Reason:** Depression

400.0 Milligram Daily Oral

Batch: **Started:** 21/01/2005 **Stopped:** 08/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205624 **Seq:** 1
Reported: 28/02/2005
Hospitalisation:
Onset Date: 15/02/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 49
DOB: 27/04/1954
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Required Visit to Doctor	Patient experienced blurred vision, eye pain, glaucoma right eye, normal 10 P left and therapeutic response unexpected (migraine recovered)	
Eye pain	Required Visit to Doctor		
Glaucoma	Required Visit to Doctor		
Therapeutic response unexpecte	Required Visit to Doctor		

Medicine Details:

EVENING PRIMROSE OIL (Other drug) **Reason:**
300.0 Milligram
Batch: **Started:** **Stopped:**

Blackmores Chewable Bio Calcium (Other drug) **Reason:**
1.0 Dose Unspecified
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205666 **Seq:** 1 **Gender:** M
Reported: 01/03/2005 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 44
Onset Date: 12/02/2005 **DOB:** 10/06/1960
Outcome: Recovered 17/02/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation	Violent outburst - detained by police.	

Medicine Details:

SOMAC (Other drug) **Reason:** Other diseases of esophagus
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

LEVETIRACETAM (Suspected) **Reason:** Convulsions
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 02/11/2004 **Stopped:** Contin

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 23/12/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also abusing alcohol and Cannabis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205723 **Seq:** 1
Reported: 02/03/2005
Hospitalisation:
Onset Date: 05/04/2004
Outcome: Not yet recovered

Gender: M
Weight: 110.00
Age: 24
DOB: 23/12/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delusion	Life	I was prescribed Zoloft after I presented at my local General practitioner?s office with symptoms of depressive disorder as indicated in DSM-IV my Gp?s advised me to take 25mg and increase the dose to 50mg after a few days, I took the 25mg as requested and about 3hrs later I could the the dreadful effects already taking place. Although my Gp indicated you may feel worse before you get better increased the dose to 50mg after a few days as requested, after about a day on the 50mg I became seriously delusional, began Dry reaching every few minutes, extreme anxiety, thoughts of killing my family, de-personalization, irrational though behaviour, rushes of cold pins and ...	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet Milligram Daily Oral

Batch: Unknown **Started:** 05/04/2004 **Stopped:** 10/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 205723 **Seq:** 1
Reported: 02/03/2005
Hospitalisation:
Onset Date: 05/04/2004
Outcome: Not yet recovered

Gender: M
Weight: 110.00
Age: 24
DOB: 23/12/1979
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
		... needle?s through my body witch I still get today. After 4days of not eating and drinking and the suicidal attempt my family rang the local ambulance who transported me to our local hospital and was immaterially told to cease Zoloft as I have had a ?so called bad reaction? and to this day I still suffer symptoms of what Zoloft did to me and see my local gp once and week and regular physiatrist visit?s Zoloft has recked my life and would love some assistance in this matter	
Anxiety	Life		
Depersonalisation	Life		
Homicidal ideation	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet | Milligram | Daily | Oral

Batch: Unknown **Started:** 05/04/2004 **Stopped:** 10/04/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205723 **Seq:** 1 **Gender:** M
Reported: 02/03/2005 **Weight:** 110.00
Hospitalisation: **Age:** 24
Onset Date: 05/04/2004 **DOB:** 23/12/1979
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Life		
Retching	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet Milligram Daily Oral

Batch: Unknown **Started:** 05/04/2004 **Stopped:** 10/04/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205774 **Seq:** 1
Reported: 07/03/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 35
DOB: 12/09/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		Caesarian section
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MAXOLON (Other drug) **Reason:**
10.0 Milligram
Batch: **Started:** 20/04/2004 **Stopped:** 15/10/2004

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 26/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 205775 is the second sequence to this report.
Patient smokes 20 per day.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205819 **Seq:** 1
Reported: 07/03/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 15/01/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 41
DOB: 28/10/1963
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression	Required Visit to Doctor	Increased depression and loss of control.	Return to brand name and
Drug ineffective	Required Visit to Doctor		
Drug therapy changed	Required Visit to Doctor		

Medicine Details:

LOSEC (Other drug) **Reason:** Other diseases of esophagus
20.0 Milligram Oral
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Xydep substituted (without patients knowledge or pharmacy advice allegedly) for Zoloft. Not ever previously used generic.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205831 **Seq:** 1
Reported: 08/03/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 67
DOB: 03/07/1937
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level above therapeutic	Caused or prolonged inpatient hospitalisation	The patient developed high Clozaril and Lithium levels whilst on Clozaril and after having commenced Celebrex. He was also on a 'fair dose' of Sertraline at the time.	
Sedation	Caused or prolonged inpatient hospitalisation	patient experience high clozapine levels and sedation on low dose of clozaril.	

Medicine Details:

LITHIUM CARBONATE (Interaction) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CELEBREX (Interaction) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:** 0

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Interaction) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 09/06/2000 **Stopped:** 07/02/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/03/2005	Serum drug level				Clozaril level of 2700 (no units, normal range 'around 1000') and a Lithium level of 1.4 (no units, normal range 'around 1').

Additional Information:

Clozaril reduced to 12.5mg/day on 14/02/05 from 600mg/day. Celebrex is drug interaction not suspected.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205831 **Seq:** 1
Reported: 08/03/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 67
DOB: 03/07/1937
Causality: Causality possible

Reaction Detail

Medicine Details:

CLOZARIL (Interaction) **Reason:**
12.0 Milligram Daily
Batch: **Started:** 14/02/2005 **Stopped:** 19/05/2005 0

Laboratory Investigations:

Additional Information:

Clozaril reduced to 12.5mg/day on 14/02/05 from 600mg/day. Celebrex is drug interaction not suspected.

Report Detail

Case Number: 205937 **Seq:** 1 **Gender:** F
Reported: 10/03/2005 **Weight:** 51.00
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 26/02/1965
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain		Cyclical treatment-During the two weeeks of therapy every month, the patient experiences breast lumpsleading up to menstruation. Her breasts feel lumpy and painful, similar to when she was breast feeding	
Breast mass		The patient experienced lumps in her breast while taking Zoloft.	Zoloft ceased.

Medicine Details:

FAMVIR (Other drug) **Reason:**
Tablet 250.0 Milligram Oral
Batch: **Started:** **Stopped:** 0

NEURONTIN (Other drug) **Reason:**
Capsule 300.0 Milligram Oral
Batch: **Started:** **Stopped:**

KEFLEX (Other drug) **Reason:**
250.0 Milligram Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Othr disorders of menstruation
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Rechallenge

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 205941 **Seq:** 1
Reported: 10/03/2005
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
Upper gastrointestinal haemorrha	Required Specialist Consultation	The patient experienced an upper gastrointestinal bleed.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206105 **Seq:** 1 **Gender:** F
Reported: 16/03/2005 **Weight:** 64.00
Hospitalisation: **Age:** 50
Onset Date: 14/02/2005 **DOB:** 03/12/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Vulval disorder Anorgasmia Atrophic vulvovaginitis Dyspareunia Sexual dysfunction		The patient experienced shrinking of the clitoris and labia minora down to one quarter of their normal size. She cannot reach orgasm and intercourse is very painful due to atrophy of the vagina.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/10/2004 S TERM **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206167 **Seq:** 1
Reported: 18/03/2005
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
Suicide attempt	Caused or prolonged inpatient hospitalisation	Patient was suicidal, attempted to kill himself and had thoughts of killing people, experienced extreme cold rushes through body	
Feeling cold	Caused or prolonged inpatient hospitalisation		
Homicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206167 **Seq:** 1
Reported: 18/03/2005
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
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206398 **Seq:** 1
Reported: 31/03/2005
Hospitalisation: Admitted to hospital
Onset Date: 01/03/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 74Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fall	Caused or prolonged inpatient hospitalisation	Multiple falls and increasing debility. Recent fall resulted in fracture to right humerus	Oxazepam weaned and Dothiepin ceased.
Asthenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:** Otr&nos disord of heart rhythm
Batch: **Started:** **Stopped:**

PROPYLTHIOURACIL (Other drug) **Reason:** Thyrotoxicosis w/o ment goiter
Batch: **Started:** **Stopped:**

CHLORVESCENT (Other drug) **Reason:** Alkalosis
Batch: **Started:** **Stopped:**

PARACETAMOL (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206398 **Seq:** 1
Reported: 31/03/2005
Hospitalisation: Admitted to hospital
Onset Date: 01/03/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 74Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

VENTOLIN (Other drug)		**Reason:**	Otr respiratory systm diseases
Batch:	**Started:**		**Stopped:**
FRUSEMIDE (Other drug)		**Reason:**	No reason given
Batch:	**Started:**		**Stopped:**
PREDNISOLONE (Other drug)		**Reason:**	Other rheumatoid arthritis
Batch:	**Started:**		**Stopped:**
FAMOTIDINE (Other drug)		**Reason:**	Other diseases of esophagus
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 206398 **Seq:** 1
Reported: 31/03/2005
Hospitalisation: Admitted to hospital
Onset Date: 01/03/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 74Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

FOSAMAX ONCE WEEKLY TABLETS (Other drug)		**Reason:**	Osteoporosis
Batch:	**Started:**		**Stopped:**
FOLIC ACID (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
METHOTREXATE (Other drug)		**Reason:**	Other rheumatoid arthritis
Batch:	**Started:**		**Stopped:**
FERRO-GRADUMET (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206398 **Seq:** 1
Reported: 31/03/2005
Hospitalisation: Admitted to hospital
Onset Date: 01/03/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 74Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

IRBESARTAN (Other drug)				**Reason:**	Essential benign hypertension	
Batch:	**Started:**				**Stopped:**	
SIMVASTATIN (Other drug)				**Reason:**	Othr&unspec metabolic diseases	
Batch:	**Started:**				**Stopped:**	
OXAZEPAM (Suspected)				**Reason:**	Anxiety neurosis	
Tablet	90.0	Milligram	Daily		Oral	
Batch:	**Started:**				**Stopped:**	
DOTHIEPIN HYDROCHLORIDE (Suspected)				**Reason:**	Depression	
	20.0	Milligram	Daily		Oral	
Batch:	**Started:**				**Stopped:**	07/04/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206398 **Seq:** 1
Reported: 31/03/2005
Hospitalisation: Admitted to hospital
Onset Date: 01/03/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 74Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	25.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206512 **Seq:** 1 **Gender:** F
Reported: 02/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 28
Onset Date: 01/06/2004 **DOB:** 28/01/1976
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
CSF pressure increased	Incapacity/disability	Lumbar puncture showed a cerbrospinal pressure of 29	
Intracranial pressure increased	Incapacity/disability	The patient experienced idiopathic intracranial hypertension, headaches and blurry vision	Referred to an ophthalmologist who recommended cessation of Zoloft. Commenced diamox 250mg qid
Visual acuity reduced	Incapacity/disability	gradual worsening of migraine headache accompanied by defective visual acuity	
Headache	Incapacity/disability		
Vision blurred	Incapacity/disability		

Medicine Details:

ZOLMITRIPTAN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

TERBUTALINE SULPHATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SALBUTAMOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 09/03/2002 **Stopped:** 09/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2005	Cerebrospinal fluid	20mmh			Lumbar puncture showed a cerebrospinal pressure of 29
02/04/2005	Magnetic				Non-inflammatory or space occupying lesion
02/04/2005	Other data				CT and MRI performed, results not available.

Additional Information:

Medical history: Obesity, Asthma, Migraine. Had migraine for over 10 years which is preceded by a visual aura that lasts up to 30 minutes

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206738 **Seq:** 1 **Gender:** M
Reported: 07/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 15/11/2002 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	The patient, who was taking Zoloft, hung himself in November 2002.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:** 15/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206797 **Seq:** 1 **Gender:** F
Reported: 08/04/2005 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 01/01/2002 **DOB:**
Outcome: Recovered 15/02/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neonatal disorder	Caused or prolonged inpatient hospitalisation	The baby experienced neonatal haemolytic anaemia associated with neutrophilia, eosinophilia and thrombocytosis.	All drugs ceased (infant and mother). Baby required blood transfusion for anaemia.
Eosinophilia	Caused or prolonged inpatient hospitalisation		
Haemolytic anaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Asphyxia of newborn,unspecif
Batch: **Started:** **Stopped:** 0

ADALAT (Suspected) **Reason:** Breast milk transfer
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Breast milk transfer
Batch: **Started:** **Stopped:**

AMOXYCILLIN SODIUM (Suspected) **Reason:** Breast milk transfer
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/04/2005	Haemoglobin		01/02/2002	63 g/L	

Additional Information:

Premature infant born at 32 weeks. Expressed breastmilk ceased and baby given formula. Mother then ceased Zoloft and re-commenced expressed breastmilk. Infant was also taking theophylline for apnoea of prematurity which is also a possible cause.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 206797 **Seq:** 1 **Gender:** F
Reported: 08/04/2005 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 01/01/2002 **DOB:**
Outcome: Recovered 15/02/2002 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutrophilia	Caused or prolonged inpatient hospitalisation		
Thrombocythaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Asphyxia of newborn,unspecif
Batch: **Started:** **Stopped:** 0

ADALAT (Suspected) **Reason:** Breast milk transfer
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Breast milk transfer
Batch: **Started:** **Stopped:**

AMOXYCILLIN SODIUM (Suspected) **Reason:** Breast milk transfer
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Premature infant born at 32 weeks. Expressed breastmilk ceased and baby given formula. Mother then ceased Zoloft and re-commenced expressed breastmilk. Infant was also taking theophylline for apnoea of prematurity which is also a possible cause.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207013 **Seq:** 1 **Gender:** M
Reported: 14/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred Ocular discomfort		The patient experienced aggravated right visual blurring and visual discomfort overnight. Symptoms were occurring about every other day	Sertraline ceased, changed to Venlafaxine.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Bilateral acute angle closure caused by supraciliary effusions associated with Venlafaxine intake. Maria Hannah Pia de Guzman, Sureka Thiagalingam, Poh Yan Ong and Ivan Goldberg. MJA 2005; 182 (3): 121-123.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207061 **Seq:** 1
Reported: 14/04/2005
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
Convulsion Drug hypersensitivity		The patient experienced a seizure and convulsions after 18 days of Zoloft, the patient's physician said she was allergic to them (Zoloft) and not to have them anymore.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207080 **Seq:** 1
Reported: 14/04/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 20/02/2005
Outcome: Recovered

Gender: F
Weight: 50.00
Age: 40
DOB: 10/06/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme abnormal Jaundice			

Medicine Details:

Remotiv (Other drug) **Reason:**
Tablet 2.8 Gram Daily Oral
Batch: **Started:** 14/02/2005 **Stopped:** 15/02/2005 0

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 17/02/2005 **Stopped:** 21/02/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previously been on Zoloft 200mg daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207110 **Seq:** 1 **Gender:** F
Reported: 15/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Life	Patient experienced worsening of suicidal thoughts/ideations after two weeks of Zoloft therapy	
Drug ineffective	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Receiving an unknown dose of Zoloft for around four weeks patient experienced worsening of suicidal thoughts/ideations after two weeks of Zoloft therapy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207186 **Seq:** 1
Reported: 19/04/2005
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 19
DOB: 28/03/1985
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eating disorder	Caused or prolonged inpatient hospitalisation	The patient was taking Zoloft at night and she stopped eating for a week. Zoloft was then taken in the morning and the patient experienced sweaty hands, increased anxiety, head spins, fainted, 'in and out' of consciousness, had an eight minute seizure on 21/03/2005 and was out of consciousness for ten minutes.	Zoloft ceased.
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 04/03/2005 **Stopped:** 22/03/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past Medical History: previous fits. Patient also taking Herbal Preparation, ingredients unknown.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207186 **Seq:** 1
Reported: 19/04/2005
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 19
DOB: 28/03/1985
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 04/03/2005 **Stopped:** 22/03/2005 0

Laboratory Investigations:

Additional Information:

Past Medical History: previous fits. Patient also taking Herbal Preparation, ingredients unknown.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207186 **Seq:** 1
Reported: 19/04/2005
Hospitalisation: Admitted to hospital
Onset Date: 04/03/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 19
DOB: 28/03/1985
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation		Maxolon
Syncope	Caused or prolonged inpatient hospitalisation		
Vertigo	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 04/03/2005 **Stopped:** 22/03/2005 0

Laboratory Investigations:

Additional Information:

Past Medical History: previous fits. Patient also taking Herbal Preparation, ingredients unknown.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207408 **Seq:** 1 **Gender:** F
Reported: 27/04/2005 **Weight:** 51.00
Hospitalisation: **Age:** 35
Onset Date: 07/04/2005 **DOB:** 23/05/1969
Outcome: Recovered 08/04/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vertigo Dry mouth		After the first dose patient developed a dry mouth and experienced vertigo, coloured lights and room moving whenever closed eyes	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram 1 time Oral
Batch: **Started:** 07/04/2005 **Stopped:** 07/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207424 **Seq:** 1 **Gender:** F
Reported: 27/04/2005 **Weight:** 51.00
Hospitalisation: Admitted to hospital **Age:** 88Y
Onset Date: 07/05/2004 **DOB:**
Outcome: Recovered 11/05/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient developed hyponatraemia.	Stop Sertraline, given Sodium chloride 0.9% 1L over 12 hours

Medicine Details:

ELOCON (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANAMAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZINC (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

STEMETIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/04/2005	Sodium		07/05/2004	118	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207424 **Seq:** 1 **Gender:** F
Reported: 27/04/2005 **Weight:** 51.00
Hospitalisation: Admitted to hospital **Age:** 88Y
Onset Date: 07/05/2004 **DOB:**
Outcome: Recovered 11/05/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

QUINALBARBITONE SODIUM (Suspected)			**Reason:**	
	300.0 Milligram		As necessary	Oral
Batch:	**Started:** 15/11/2003		**Stopped:**	07/05/2004
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	
Tablet	50.0 Milligram		Daily	Oral
Batch:	**Started:** 05/05/2004		**Stopped:**	07/05/2004
BRUFEN (Suspected)			**Reason:**	
Tablet	400.0 Milligram		Daily	Oral
Batch:	**Started:** 15/11/2003		**Stopped:**	06/05/2004

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207427 **Seq:** 1 **Gender:** M
Reported: 27/04/2005 **Weight:** 0.00
Hospitalisation: Treated in outpatient department only. **Age:** 68Y
Onset Date: 26/02/2004 **DOB:**
Outcome: Recovered 19/03/2004 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		The patient experienced increasing involuntary dyskinetic movements.	Norfloxacin and Sertraline ceased. Given Benztropine

Medicine Details:

OMEPRAZOLE (Other drug)		**Reason:**	Other diseases of esophagus
Batch:	**Started:**		**Stopped:**
MULTIVITAMINS (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
GLICLAZIDE (Other drug)		**Reason:**	Diabetes mellitus
Batch:	**Started:**		**Stopped:**
LIGNOCAINE (Other drug)		**Reason:**	Otr&unspec oral soft tissu dis
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/04/2005	Computerised				CT Brain (N) 17/02/04.

Additional Information:

Report 207429 is the second sequence to this report.

Report Detail

Case Number: 207427 **Seq:** 1 **Gender:** M
Reported: 27/04/2005 **Weight:** 0.00
Hospitalisation: Treated in outpatient department only. **Age:** 68Y
Onset Date: 26/02/2004 **DOB:**
Outcome: Recovered 19/03/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

DAKTARIN (Other drug)		**Reason:**	Otr&unspec oral soft tissu dis	
Batch:	**Started:**		**Stopped:**	
FLUCONAZOLE (Other drug)		**Reason:**	Otr&unspec oral soft tissu dis	
Batch:	**Started:**		**Stopped:**	0
METOCLOPRAMIDE HYDROCHLORIDE (Other drug)		**Reason:**		
Batch:	**Started:**		**Stopped:**	
MS CONTIN (Other drug)		**Reason:**		
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:

Report 207429 is the second sequence to this report.

Report Detail

Case Number: 207427 **Seq:** 1 **Gender:** M
Reported: 27/04/2005 **Weight:** 0.00
Hospitalisation: Treated in outpatient department only. **Age:** 68Y
Onset Date: 26/02/2004 **DOB:**
Outcome: Recovered 19/03/2004 **Causality:** Causality possible

Reaction Detail

Medicine Details:

MORPHINE SULPHATE (Other drug)			**Reason:**	
Batch:	**Started:**			**Stopped:**
ZOLOFT (Suspected)			**Reason:**	Depression
Tablet	50.0 Milligram	Daily		Oral
Batch:	**Started:** 18/02/2004			**Stopped:** 17/03/2004
NORFLOXACIN (Suspected)			**Reason:**	Othr diseases of urinary tract
Tablet	800.0 Milligram	Daily		Oral
Batch:	**Started:** 18/02/2004			**Stopped:** 17/03/2004

Laboratory Investigations:

Additional Information:

Report 207429 is the second sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207527 **Seq:** 1 **Gender:** F
Reported: 02/05/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 80
Onset Date: 01/04/2005 **DOB:** 01/02/1925
Outcome: Recovered 04/04/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	The patient experienced the onset of hyponatremia secondary to suspected syndrome of inappropriate antidiuretic hormone one week after commencing Zoloft.	Zoloft ceased.
Inappropriate antidiuretic hormon	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Oral
Batch: **Started:** 23/03/2005 **Stopped:** 02/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207597 **Seq:** 1 **Gender:** M
Reported: 04/05/2005 **Weight:** 53.00
Hospitalisation: Admitted to hospital **Age:** 87
Onset Date: 04/04/2005 **DOB:** 16/09/1917
Outcome: Recovered 20/04/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coagulopathy	Caused or prolonged inpatient hospitalisation	Patient experienced lower leg purpura, acute coagulopathy suspected with leg oedema, INR 2, bleed from head wound, has CRF and worsened on admission detected, probable vasculitis suspected, microscopic haematuria and increased ESR and decreased Hb (8.3).	Ceased Aspirin and started Vit K tabs, Ceased Zoloft and Zocor
Anaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RANI 2 (Other drug) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

KEFLEX (Suspected) **Reason:** Chronic ulcer of skin
Capsule 2.0 Gram Daily Oral
Batch: **Started:** 23/03/2005 **Stopped:** 02/04/2005

ASPIRIN (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 07/04/2005

ZOCOR (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 13/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has history of anaemia, psoriasis, reactive depression, infected leg ulcer and hypertension.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207597 **Seq:** 1 **Gender:** M
Reported: 04/05/2005 **Weight:** 53.00
Hospitalisation: Admitted to hospital **Age:** 87
Onset Date: 04/04/2005 **DOB:** 16/09/1917
Outcome: Recovered 20/04/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematuria	Caused or prolonged inpatient hospitalisation		
Oedema	Caused or prolonged inpatient hospitalisation		
Renal failure chronic	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 16/08/2004 **Stopped:** 13/04/2005

Laboratory Investigations:

Additional Information:
Patient has history of anaemia, psoriasis, reactive depression, infected leg ulcer and hypertension.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207597 **Seq:** 1 **Gender:** M
Reported: 04/05/2005 **Weight:** 53.00
Hospitalisation: Admitted to hospital **Age:** 87
Onset Date: 04/04/2005 **DOB:** 16/09/1917
Outcome: Recovered 20/04/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vasculitis	Caused or prolonged inpatient hospitalisation		
Wound haemorrhage	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RANI 2 (Other drug) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

KEFLEX (Suspected) **Reason:** Chronic ulcer of skin
Capsule 2.0 Gram Daily Oral
Batch: **Started:** 23/03/2005 **Stopped:** 02/04/2005

ASPIRIN (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 07/04/2005

ZOCOR (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 13/04/2005

Laboratory Investigations:

Additional Information:
Patient has history of anaemia, psoriasis, reactive depression, infected leg ulcer and hypertension.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207597 **Seq:** 1 **Gender:** M
Reported: 04/05/2005 **Weight:** 53.00
Hospitalisation: Admitted to hospital **Age:** 87
Onset Date: 04/04/2005 **DOB:** 16/09/1917
Outcome: Recovered 20/04/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 16/08/2004 **Stopped:** 13/04/2005

Laboratory Investigations:

Additional Information:
Patient has history of anaemia, psoriasis, reactive depression, infected leg ulcer and hypertension.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207644 **Seq:** 1 **Gender:** M
Reported: 06/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 14/04/2005 **DOB:** 08/06/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	The patient experienced seizures during Clopine treatment.	Clozapine dose decreased.
Dystonia	Caused or prolonged inpatient hospitalisation	experienced involuntary movement of arms	Congentin 2mg

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

CLOPINE (Suspected) **Reason:**
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 03/12/2001 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207723 **Seq:** 1
Reported: 11/05/2005
Hospitalisation: Admitted to hospital
Onset Date: 15/03/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 57
DOB: 10/12/1947
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed	Life	Changed from Zoloft to Xydep	
Anaphylactic reaction	Life	Patient experienced a suspected anaphylactic reaction with throat oedema.	Patient required treatment in the intensive care. Given IV adrenalin, antihistamine later
Blood pressure increased	Life	to 190	
Pharyngeal oedema	Life		

Medicine Details:

Xydep (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The physician states the patient had several earlier, more minor episodes on unspecified dates. Patient has alergy to Clindamycin and Penicillin

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207730 **Seq:** 1 **Gender:** F
Reported: 11/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 53
Onset Date: 08/02/2005 **DOB:** 19/09/1951
Outcome: Recovered 10/02/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancreatitis acute	Caused or prolonged inpatient hospitalisation	Patient experienced acute pancreatitis.	Patient was removed from Zoloft and Zocor and is reported to be taking Lipitor and Cipramil
Blood amylase increased	Caused or prolonged inpatient hospitalisation		
Lipase increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PREMIA 5 (Other drug) **Reason:**
Batch: **Started:** 28/10/2004 **Stopped:** 0

NICABATE (Other drug) **Reason:**
14.0 Gram Percutaneous
Batch: **Started:** **Stopped:**

PANADOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOCOR (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207730 **Seq:** 1 **Gender:** F
Reported: 11/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 53
Onset Date: 08/02/2005 **DOB:** 19/09/1951
Outcome: Recovered 10/02/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 08/02/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207768 **Seq:** 1 **Gender:** F
Reported: 12/05/2005 **Weight:** 74.00
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 02/06/1968
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Incapacity/disability	The patient suffered heart palpitations whilst on Zoloft. The dose was reduced and she felt that if she turned her head she would fall. She needed to be supported and had to hire a walking frame. She also experienced weakness in the arm, her muscles were rigid, she was 'like walking around with cerebral palsy' and had a constant headache. She states that every time her Zoloft dose was reduced, the withdrawal symptoms would come back after two days. She also fell and now has a sore back. She also suffered mood swings, aggression and impulse impairment.	Zoloft dose decreased more

Medicine Details:

XANAX (Other drug) **Reason:**
6.0 Milligram
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 15/01/2003 **Stopped:** 15/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient states the eveytime her zoloft dose was reduced, the withdrawal symptoms would come back after two days. Reaction occurred when zoloft dose reduced by 50mg every four days.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207768 **Seq:** 1 **Gender:** F
Reported: 12/05/2005 **Weight:** 74.00
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 02/06/1968
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression	Incapacity/disability		
Drug withdrawal syndrome	Incapacity/disability		
Fall	Incapacity/disability		
Gait disturbance	Incapacity/disability		
Mood swings	Incapacity/disability		
Muscle rigidity	Incapacity/disability		

Medicine Details:

XANAX (Other drug) **Reason:**
6.0 Milligram
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 15/01/2003 **Stopped:** 15/03/2005

Laboratory Investigations:

Additional Information:

The patient states the eveytime her zoloft dose was reduced, the withdrawal symptoms would come back after two days. Reaction occurred when zoloft dose reduced by 50mg every four days.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207768 **Seq:** 1 **Gender:** F
Reported: 12/05/2005 **Weight:** 74.00
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 02/06/1968
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscular weakness	Incapacity/disability		
Palpitations	Incapacity/disability		

Medicine Details:

XANAX (Other drug) **Reason:**
6.0 Milligram
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 15/01/2003 **Stopped:** 15/03/2005

Laboratory Investigations:

Additional Information:

The patient states the eveytime her zoloft dose was reduced, the withdrawal symptoms would come back after two days. Reaction occurred when zoloft dose reduced by 50mg every four days.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 207887 **Seq:** 1
Reported: 16/05/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: M
Weight: 37.00
Age: 11
DOB: 22/08/1993
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema nodosum		Erythema nodosum type reaction	

Medicine Details:

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

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 25/10/2004 **Stopped:** 05/11/2004

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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208057 **Seq:** 1
Reported: 20/05/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 10/05/2001
Outcome: Not yet recovered

Gender: F
Weight: 53.00
Age: 70
DOB: 27/01/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Incapacity/disability	When the dose of Zoloft was increased the patient experienced hot, drenching sweats, insomnia, nightmares and short term memory loss	B complex.
Amnesia	Incapacity/disability		
Hyperhidrosis	Incapacity/disability		
Insomnia	Incapacity/disability		
Nightmare	Incapacity/disability		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 07/11/2000 **Stopped:** 20/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose was increased from 25 to 50mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208141 **Seq:** 1 **Gender:** F
Reported: 24/05/2005 **Weight:** 73.00
Hospitalisation: **Age:** 48
Onset Date: 07/04/2005 **DOB:** 13/06/1956
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Depression		Worsening of depression when switching from Zoloft 100mg to Xydep 100mg. Depression improved once again upon switching back to Zoloft	Changed back to Zoloft.

Medicine Details:

Simvar (Other drug)			**Reason:**	Othr&unspec metabolic diseases
Tablet	80.0	Milligram	Daily	Oral
Batch:	**Started:**	19/03/2005	**Stopped:**	
OROXINE (Other drug)			**Reason:**	Myxedema
Tablet	50.0	Microgram	Daily	Oral
Batch:	**Started:**		**Stopped:**	
Xydep (Suspected)			**Reason:**	Depression
Tablet	100.0	Milligram	Daily	Oral
Batch:	**Started:**	31/03/2005	**Stopped:**	05/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208142 **Seq:** 1 **Gender:** F
Reported: 24/05/2005 **Weight:** 70.00
Hospitalisation: **Age:** 38
Onset Date: 05/05/2005 **DOB:** 20/02/1967
Outcome: Recovered 07/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Sertraline and Tramadol triggered a seizure (tonic clonic). Two other fits last 3 weeks since started on Tramadol 3 weeks ago. Symptoms of suspected serotonin syndrome - neurologic physiologic as well as seizures.	Stop all medications.
Convulsion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Osteoarthritis
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

LARGACTIL (Interaction) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

LITHIUM CARBONATE (Other drug) **Reason:**
Tablet 1.0 Gram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had a MVA five years ago with head injuries.

Report Detail

Case Number: 208142 **Seq:** 1 **Gender:** F
Reported: 24/05/2005 **Weight:** 70.00
Hospitalisation: **Age:** 38
Onset Date: 05/05/2005 **DOB:** 20/02/1967
Outcome: Recovered 07/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Seretide 250/50 Accuhaler (Other drug) **Reason:**

Inhalation 4.0 Dose Unspecified Daily Inhalation

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

Laboratory Investigations:

Additional Information:

The patient had a MVA five years ago with head injuries.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208186 **Seq:** 1 **Gender:** F
Reported: 26/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 28/04/2005 **DOB:**
Outcome: Recovered 09/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Disturbance in attention Feeling abnormal Sleep disorder		Stabilised on Zoloft changed to Xydep, then experienced severly disturbed sleep, nightmares, vacancy feeling and lack of concentration	Ceased medication changed back to Zoloft.

Medicine Details:

Xydep (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 28/04/2005 **Stopped:** 06/05/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208197 **Seq:** 1
Reported: 26/05/2005
Hospitalisation: Admitted to hospital
Onset Date: 10/05/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 74
DOB: 09/09/1930
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient experienced hyponatraemia over 2 days folowing increase of Zoloft from 25mg to 50mg	Zoloft ceased. Fluid restriction.
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ATORVASTATIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANTOPRAZOLE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/05/2005	Sodium				Sodium levels - 117.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208197 **Seq:** 1
Reported: 26/05/2005
Hospitalisation: Admitted to hospital
Onset Date: 10/05/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 74
DOB: 09/09/1930
Causality: Causality possible

Reaction Detail

Medicine Details:

Seretide 500/50 Accuhaler (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
MIXTARD 30/70 (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
PARACETAMOL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
COLOXYL WITH SENNA (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208197 **Seq:** 1
Reported: 26/05/2005
Hospitalisation: Admitted to hospital
Onset Date: 10/05/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 74
DOB: 09/09/1930
Causality: Causality possible

Reaction Detail

Medicine Details:

MS CONTIN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
LACTULOSE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
PREDNISOLONE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
INDOMETHACIN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208197 **Seq:** 1
Reported: 26/05/2005
Hospitalisation: Admitted to hospital
Onset Date: 10/05/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 74
DOB: 09/09/1930
Causality: Causality possible

Reaction Detail

Medicine Details:

DIAZEPAM (Other drug)			**Reason:**	
Batch:	**Started:**		**Stopped:**	
MICROLAX ENEMA (Other drug)			**Reason:**	
Batch:	**Started:**		**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	
Tablet	50.0 Milligram	Daily	Oral	
Batch:	**Started:** 10/05/2005		**Stopped:** 11/05/2005	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208206 **Seq:** 1 **Gender:** F
Reported: 26/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 18Y
Onset Date: 09/05/2005 **DOB:**
Outcome: Recovered 10/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Patient experienced jerky movement.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 1.0 Dose Unspecified 1 time Oral
Batch: **Started:** 09/05/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208225 **Seq:** 1
Reported: 27/05/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 36
DOB: 25/07/1968
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia	Caused or prolonged inpatient hospitalisation	Patient experienced the onset of constant hot flushes, shaking, dizziness, sweaty palms and feet, tremors, vomiting, tingling in the hands and feet, patient also states she could not sleep for three nights.	Zoloft was ceased.
Dizziness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VOLTAREN (Other drug) **Reason:**
Tablet 100.0 Milligram Oral
Batch: **Started:** **Stopped:** 0

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 24/04/2005 **Stopped:** 28/04/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208225 **Seq:** 1 **Gender:** F
Reported: 27/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 25/07/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Paraesthesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VOLTAREN (Other drug) **Reason:**
Tablet 100.0 Milligram Oral
Batch: **Started:** **Stopped:** 0

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 24/04/2005 **Stopped:** 28/04/2005 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208225 **Seq:** 1 **Gender:** F
Reported: 27/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 36
Onset Date: **DOB:** 25/07/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VOLTAREN (Other drug) **Reason:**
Tablet 100.0 Milligram Oral
Batch: **Started:** **Stopped:** 0

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 24/04/2005 **Stopped:** 28/04/2005 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208416 **Seq:** 1 **Gender:** M
Reported: 02/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 51Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse		Three weeks after beginning treatment with Seroquel the patient collapsed at home.	Taken to the emergency room.

Medicine Details:

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

SEROQUEL (Suspected) **Reason:** Otr spec symp psychopathol nec
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking cholesterol lowering drugs. Concomitant disease: diabetes mellitus

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208448 **Seq:** 1 **Gender:** M
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 22/05/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Homicidal ideation Suicidal ideation Suicide attempt		The patient had severe akathisia on Zoloft, developed serious homicidal ideation and suicidal ideation.	Zoloft ceased.

Medicine Details:

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208483 **Seq:** 1 **Gender:** F
Reported: 03/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 38Y
Onset Date: 12/04/2005 **DOB:**
Outcome: Recovered 12/05/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epilepsy		The patient experienced drug induced epilepsy and seizures.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208653 **Seq:** 1 **Gender:** M
Reported: 10/06/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 84
Onset Date: 02/05/2005 **DOB:** 02/07/1920
Outcome: Recovered 10/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient experienced hyponatrenmia, hyperkalaemia, confusion.	
Confusional state	Caused or prolonged inpatient hospitalisation		
Hyperkalaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OROXINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PROPRANOLOL HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CALTRATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/06/2005	Potassium		02/05/2005	6.1	
10/06/2005	Sodium		02/05/2005	115	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208653 **Seq:** 1 **Gender:** M
Reported: 10/06/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 84
Onset Date: 02/05/2005 **DOB:** 02/07/1920
Outcome: Recovered 10/05/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ACTONEL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
RANITIDINE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
VAGIFEM (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
OTRIVIN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208653 **Seq:** 1 **Gender:** M
Reported: 10/06/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 84
Onset Date: 02/05/2005 **DOB:** 02/07/1920
Outcome: Recovered 10/05/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

PANAMAX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
PANADEINE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
LATANOPROST (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
SERTRALINE HYDROCHLORIDE (Suspected)		**Reason:**	Depression
Tablet	50.0 Milligram	Daily	Oral
Batch:	**Started:** 27/04/2005		**Stopped:** 02/05/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208653 **Seq:** 1 **Gender:** M
Reported: 10/06/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 84
Onset Date: 02/05/2005 **DOB:** 02/07/1920
Outcome: Recovered 10/05/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

TELMISARTAN (Suspected) **Reason:** Essential benign hypertension
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 02/05/2005 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208655 **Seq:** 1 **Gender:** F
Reported: 10/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 42Y
Onset Date: 12/06/2004 **DOB:**
Outcome: Recovered 25/03/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Incapacity/disability	withdrawal side effects (extreme dizziness) from Zoloft medication. I began taking the zoloft 50mg/day for PND. I was warned about possible side effects during the first month on the medication. During the time I took the zoloft I did suffer with some of the more common side effects mentioned in the information brochure in the pack. I was not warned about the possibilty of becoming addicted to these tablets. After 6 months my doctor advised me to start decreasing my dosage by halving one tablet once a week, and continuing this until I was only on 25mg/day. Almost immediately I suffered with dizziness to the ...	nil

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: 414724431 **Started:** 27/12/2003 **Stopped:** 31/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208655 **Seq:** 1 **Gender:** F
Reported: 10/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 42Y
Onset Date: 12/06/2004 **DOB:**
Outcome: Recovered 25/03/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
		... extent that I could not drive the car anymore. This continued for about 3 months (long after I had stabilized on 25mg/day), before easing but not disappearing. My doctor suggested I withdraw more slowly, and not drive when I felt this way. After this time I started a very slow withdrawal by using a razor blade to shave a small amount off the tablets, enough for a couple of weeks at a time, gradually decreasing my dose. This allowed me to keep the dosage steady rather than jumping up & down (eg from 50 - 25mg) which seemed to aggravate the condition. This process took another 5 months, and then the dizziness another 2 months to fully stop after all medication was finished. I have ...	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: 414724431 **Started:** 27/12/2003 **Stopped:** 31/01/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208655 **Seq:** 1 **Gender:** F
Reported: 10/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 42Y
Onset Date: 12/06/2004 **DOB:**
Outcome: Recovered 25/03/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Incapacity/disability	... never suffered before or since with this dizziness. I have recently done some research on this side effect and found it is quite common, and I'm concerned that patients are not being warned about this possibilty, or helped through it. Getting accurate dosage was important in lessening symptoms, yet this was difficult to do with the size of the tablet. I spoke to diferent pharmacisits & my doctor about the problem yet no one offered any advice	nil

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: 414724431 **Started:** 27/12/2003 **Stopped:** 31/01/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208726 **Seq:** 1 **Gender:** F
Reported: 16/06/2005 **Weight:** 80.00
Hospitalisation: **Age:** 57
Onset Date: 29/04/2005 **DOB:** 01/09/1947
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Confusional state Drug therapy changed Headache Mental status changes		Patient felt giddy with the first dose of Xydep, body is making lot of mucous, dizziness, headaches, indecisiveness, confusion. Drug therapy changed (patient was taking Zoloft since November 2004 and was OK and stabilised had no side	

Medicine Details:

Xydep (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 29/04/2005 **Stopped:** 31/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208891 **Seq:** 1
Reported: 22/06/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: U
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension	Caused or prolonged inpatient hospitalisation	The patient was using Zoloft, which 'upset my blood pressure' and he/she experienced very cold hands and feet.	Ceased antidepressant medication

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 208952 **Seq:** 1 **Gender:** F
Reported: 22/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 45Y
Onset Date: 20/10/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Hyponatremia.	

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 15/04/2004 **Stopped:** 20/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/06/2005	Sodium		20/10/2004	128	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209221 **Seq:** 1 **Gender:** M
Reported: 29/06/2005 **Weight:** 75.00
Hospitalisation: **Age:** 73
Onset Date: 01/03/2001 **DOB:** 02/09/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	The patient experienced abnormal bleeding from the penis, fever, sweats, fits, wheezing, difficulty breathing, fast hearbeat, muscle stiffness, dry mouth, 'feeling sick', tiredness, hot flushes and was 'generally not well'. He also experienced agitation, nervousness, loss of appetite and lack of concentration. He stated that his vision has been affected. He has difficulty at times passing urine and has tingling of the arms, hands, legs and upper part of the body. During the period from 2001 when he first started Zoloft he had many blackouts, fainting and fits.	Zoloft dosage reduced and will be ceased by the end of June 2005

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** L TERM **Stopped:** Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had an operation for en enlarged prostate

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209221 **Seq:** 1 **Gender:** M
Reported: 29/06/2005 **Weight:** 75.00
Hospitalisation: **Age:** 73
Onset Date: 01/03/2001 **DOB:** 02/09/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Caused or prolonged inpatient hospitalisation		
Convulsion	Caused or prolonged inpatient hospitalisation		
Disturbance in attention	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** L TERM **Stopped:** Continuing.

Laboratory Investigations:

Additional Information:
Had an operation for en enlarged prostate

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209221 **Seq:** 1 **Gender:** M
Reported: 29/06/2005 **Weight:** 75.00
Hospitalisation: **Age:** 73
Onset Date: 01/03/2001 **DOB:** 02/09/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Dysuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** L TERM **Stopped:** Continuing.

Laboratory Investigations:

Additional Information:
Had an operation for en enlarged prostate

Report Detail

Case Number: 209221 **Seq:** 1 **Gender:** M
Reported: 29/06/2005 **Weight:** 75.00
Hospitalisation: **Age:** 73
Onset Date: 01/03/2001 **DOB:** 02/09/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue	Caused or prolonged inpatient hospitalisation		
Heart rate increased	Caused or prolonged inpatient hospitalisation		
Hot flush	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** L TERM **Stopped:** Continuing.

Laboratory Investigations:

Additional Information:

Had an operation for en enlarged prostate

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209221 **Seq:** 1 **Gender:** M
Reported: 29/06/2005 **Weight:** 75.00
Hospitalisation: **Age:** 73
Onset Date: 01/03/2001 **DOB:** 02/09/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Malaise	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** L TERM **Stopped:** Continuing.

Laboratory Investigations:

Additional Information:
Had an operation for en enlarged prostate

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209221 **Seq:** 1 **Gender:** M
Reported: 29/06/2005 **Weight:** 75.00
Hospitalisation: **Age:** 73
Onset Date: 01/03/2001 **DOB:** 02/09/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Caused or prolonged inpatient hospitalisation		
Post procedural haemorrhage	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** L TERM **Stopped:** Continuing.

Laboratory Investigations:

Additional Information:
Had an operation for en enlarged prostate

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209221 **Seq:** 1 **Gender:** M
Reported: 29/06/2005 **Weight:** 75.00
Hospitalisation: **Age:** 73
Onset Date: 01/03/2001 **DOB:** 02/09/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation		
Visual disturbance	Caused or prolonged inpatient hospitalisation		
Wheezing	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** L TERM **Stopped:** Continuing.

Laboratory Investigations:

Additional Information:
Had an operation for en enlarged prostate

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209341 **Seq:** 1 **Gender:** M
Reported: 30/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 75
Onset Date: 19/02/2005 **DOB:** 18/03/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme increased		The patient experienced raised liver enzymes on blood results.	Sertraline ceased.

Medicine Details:

CYANOCOBALAMIN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
COLOXYL WITH SENNA (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
SORBITOL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
TENOPT (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/06/2005	ALT = SGPT	0-55	19/02/2005	269	
30/06/2005	ALT = SGPT	0-55	03/03/2005	35	
30/06/2005	AST = SGOT	0-45	19/02/2005	164	
30/06/2005	AST = SGOT	0-45	03/03/2005	17	
30/06/2005	Bilirubin	6-24	19/02/2005	25	
30/06/2005	Bilirubin	6-24	03/03/2005	9	
30/06/2005	Creatinine	0.050-0.120	03/03/2005	0.100	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209341 **Seq:** 1 **Gender:** M
Reported: 30/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 75
Onset Date: 19/02/2005 **DOB:** 18/03/1929
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Medicine Details:

PERICYAZINE (Other drug) **Reason:**

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

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 08/02/2005 **Stopped:** 20/02/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
30/06/2005	GGT = SGGT = [illegible]	0-60	19/02/2005	356	
30/06/2005	GGT = SGGT = [illegible]	0-60	03/03/2005	175	
30/06/2005	Lactate	110-230	19/02/2005	267	
30/06/2005	Lactate	110-230	03/03/2005	176	
30/06/2005	SAP = ALP	30-110	19/02/2005	280	
30/06/2005	SAP = ALP	30-110	03/03/2005	148	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209481 **Seq:** 1 **Gender:** M
Reported: 05/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: 19/05/2005 **DOB:** 23/04/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	The patient was found confused and agitated at home by a family member and had not been compliant with his antipsychotic medications for a few days. The GCS score was 14; he had a blunt affect and slow speech on admission. Suspected neuroleptic malignant syndrome and weight increased.	Treated with IV Saline, Sodium Bicarbonate and Valium. All Antipsychotic medications discontinued.
Blood creatine phosphokinase in	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOCOR (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet Oral
Batch: **Started:** 07/05/2003 **Stopped:**

RISPERDAL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** 15/05/2001 **Stopped:** 19/05/2005

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2005	Creatine [illegible]		20/05/2005	1430	
05/07/2005	Creatine [illegible]		23/05/2005	2250	
05/07/2005	Creatine [illegible]		25/05/2005	467	
05/07/2005	Creatinine		20/05/2005	101	
05/07/2005	Creatinine		25/05/2005	76	
05/07/2005	Other data		20/05/2005	291	Lactic Dehydrogenase.
05/07/2005	Urea		25/05/2005	2.1	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209481 **Seq:** 1 **Gender:** M
Reported: 05/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 32
Onset Date: 19/05/2005 **DOB:** 23/04/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOCOR (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet Oral
Batch: **Started:** 07/05/2003 **Stopped:**

RISPERDAL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** 15/05/2001 **Stopped:** 19/05/2005

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2005	White blood cells		20/05/2005	11.5	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209483 **Seq:** 1 **Gender:** F
Reported: 05/07/2005 **Weight:** 87.00
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 26/01/1968
Outcome: Recovered 21/05/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Dizziness Emotional disorder Malaise		Within two days of changing from Zoloft to Xydep the patient experienced dizzy spells, was very emotional and light headed and felt really unwell	Ceased Xydep, changed back to Zoloft.

Medicine Details:

Xydep (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 16/05/2005 **Stopped:** 19/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209484 **Seq:** 1
Reported: 05/07/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 05/06/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Anxiety Depression Panic attack		The patient's prescription for Zoloft was filled with the less expensive brand, Xydep. She experienced anxiety, depression and panic attack.	Ceased Xydep.

Medicine Details:

Xydep (Suspected) **Reason:**
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209778 **Seq:** 1 **Gender:** M
Reported: 13/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 19Y
Onset Date: 01/07/2005 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Aggression		The patient became violent after taking Xydep 100mg (he was on Zoloft 100mg). He was beating up residents of the respite facility.	Ceased Xydep, changed back to Zoloft.

Medicine Details:

Xydep (Suspected) **Reason:** Other atyp forms schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 25/06/2005 **Stopped:** 01/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Xydep 100mg has colouring in coating.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209801 **Seq:** 1
Reported: 13/07/2005
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 60.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Incapacity/disability	The patient experienced tinnitus two days after commencing Zoloft.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 01/05/2005 **Stopped:** 06/05/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous tinnitus on some medication but resolved on cessation ofmed. Current tinniuts not resolving after cessation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 209983 **Seq:** 1 **Gender:** M
Reported: 20/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered 01/06/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eye movement disorder	Incapacity/disability	Patient experienced, after starting Zoloft in 2003, that his right eye became more twisted (previously reported as twisted eye) and moved independently of left eye, and photophobia increased.	Ceased Zoloft.
Photophobia	Incapacity/disability		

Medicine Details:

MERSYNDOL (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Unspecified neurosis
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 15/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210034 **Seq:** 1 **Gender:** F
Reported: 21/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 19/05/2005 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Drug ineffective Fatigue		Changed from Zoloft to Xydep, found made her very tired and not as effective .	Changed back to Zoloft.

Medicine Details:

Xydep (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms left when she changed back to Zoloft. Three similar complaints from other patients, all recovered when changed back to Zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210083 **Seq:** 1 **Gender:** F
Reported: 25/07/2005 **Weight:** 80.00
Hospitalisation: **Age:** 34
Onset Date: 23/06/2005 **DOB:** 06/08/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Incapacity/disability	Approximately two hours after first dose of Zoloft, patient became anxious, described as "anxiety through her whole body" and experienced hot flushes. After ten minutes of lying down these side effects subsided but returned an hour later. Side effects have now completely subsided, however, she now feels slightly light-headed and	Ceased Zoloft.
Dizziness	Incapacity/disability		
Hot flush	Incapacity/disability		

Medicine Details:

LIPITOR (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 23/06/2005 **Stopped:** 23/06/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210105 **Seq:** 1 **Gender:** F
Reported: 26/07/2005 **Weight:** 45.00
Hospitalisation: Required a visit to the doctor **Age:** 39
Onset Date: 08/07/2005 **DOB:** 23/09/1965
Outcome: Recovered 08/07/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Dyspnoea Mania Rash Tachycardia Tremor		Patient developed urticarial like skin rash then shakiness, shortness of breath, panic with hyperventilation and tachycardia 148/min	Treated with IV Valium and IV Hydrocortisone.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 05/07/2005 **Stopped:** 08/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210225 **Seq:** 1
Reported: 28/07/2005
Hospitalisation: Admitted to hospital
Onset Date: 11/07/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 86
DOB: 09/07/1919
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Acute serotonin syndrome suspected induced by combination of Tramadol and Sertraline	Ceased Zydol.

Medicine Details:

CLOPIDOGREL (Other drug) **Reason:** Transient cereb isch no hypert
75.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

OMEPRAZOLE (Other drug) **Reason:** Ulcer of duodenum w/o ment perf
20.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

PRAVACHOL (Other drug) **Reason:** Othr&unspec metabolic diseases
40.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Zydol (Suspected) **Reason:** Pain
Capsule 50.0 Milligram As necessary Oral
Batch: **Started:** 26/06/2005 **Stopped:** 11/07/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Relevant history: Had Zydol previously without Xydep concurrently without s/effect.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210225 **Seq:** 1
Reported: 28/07/2005
Hospitalisation: Admitted to hospital
Onset Date: 11/07/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 86
DOB: 09/07/1919
Causality: Causality probable

Reaction Detail

Medicine Details:

Xydep (Suspected)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**		L TERM	**Stopped:**	

Laboratory Investigations:

Additional Information:

Relevant history: Had Zydol previously without Xydep concurrently without s/effect.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210446 **Seq:** 1 **Gender:** F
Reported: 05/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 35Y
Onset Date: 08/07/2005 **DOB:**
Outcome: Recovered 08/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Swelling face	Caused or prolonged inpatient hospitalisation	Patient experienced a rash, facial swelling, hyperventilation, numbing fingers, panic, axiexty "jumbled speech and thoughts".	Treated with Solu-Cortef 250mg, oxygen via a mask, Valium IV and Promethazine IM. Zoloft ceased
Panic reaction	Caused or prolonged inpatient hospitalisation	Sensation of doom	
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation	Ten days after stopping Zoloft, the patients heart rate was increased and hse a a severe rash on her body	

Medicine Details:

XANAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PREMIA 5 (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DAIVONEX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ADVANTAN (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210446 **Seq:** 1 **Gender:** F
Reported: 05/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 35Y
Onset Date: 08/07/2005 **DOB:**
Outcome: Recovered 08/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation		
Hyperventilation	Caused or prolonged inpatient hospitalisation		
Hypoaesthesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 03/06/2005 **Stopped:** 08/07/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210446 **Seq:** 1 **Gender:** F
Reported: 05/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 35Y
Onset Date: 08/07/2005 **DOB:**
Outcome: Recovered 08/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

XANAX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
PREMIA 5 (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
DAIVONEX (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
ADVANTAN (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210446 **Seq:** 1 **Gender:** F
Reported: 05/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 35Y
Onset Date: 08/07/2005 **DOB:**
Outcome: Recovered 08/07/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 03/06/2005 **Stopped:** 08/07/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210655 **Seq:** 1 **Gender:** M
Reported: 12/08/2005 **Weight:** 118.00
Hospitalisation: Required a visit to the doctor **Age:** 62
Onset Date: 12/07/2005 **DOB:** 28/02/1943
Outcome: Recovered 28/08/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		The patient experienced photosensitisation whilst on Zoloft. He developed a rash over his cheek bones. Both cheeks were affected, the left more than the right, with red, warm, swollen cheeks and skin exfoliation.	Sigmacort cream, sunscreen and Prednisolone.

Medicine Details:

VOLTAREN (Other drug) **Reason:** Osteoarthritis
Batch: **Started:** **Stopped:**

STILNOX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PEPCIDINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 29/04/2005 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 210657 is the second sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210671 **Seq:** 1 **Gender:** F
Reported: 12/08/2005 **Weight:** 105.00
Hospitalisation: Required a visit to the doctor **Age:** 54
Onset Date: 27/07/2005 **DOB:** 17/10/1950
Outcome: Recovered 02/08/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain		The patient experienced retrosternal chest pain on 27 July 2005 - 2 episodes lasting	

Medicine Details:

COLCHICINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 14/07/2005 **Stopped:** 01/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: Achilles tendonitis - no NSAID's used. Allergies: Erythromycin - swollen mouth and tongue. Mysteclin - rash and swelling. NSAID's - gastric ulcer. Nystatin - swelling and rash. Penicillin - anaphylaxis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210826 **Seq:** 1 **Gender:** F
Reported: 17/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 60
Onset Date: **DOB:** 21/07/1945
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Colitis Constipation Diarrhoea Headache Muscle spasms		Patient experienced colitis microscopic, muscle spasms, constipation and severe headache. Diarrhoea cease after Zoloft was stopped	Treated with Salazopyrin and Prednisolone. Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** S TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/08/2005	Other data				Colonoscopy - diagnosed with microscopic colitis.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210870 **Seq:** 1 **Gender:** M
Reported: 18/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		The patient feels more suicidal whilst on Zoloft than he does on any other	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210925 **Seq:** 1 **Gender:** F
Reported: 18/08/2005 **Weight:** 52.00
Hospitalisation: **Age:** 47
Onset Date: 29/06/2005 **DOB:** 19/07/1957
Outcome: Recovered 11/08/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis Anorexia Dysgeusia Fatigue Liver function test abnormal		Patient developed hepatitis and liver function tests raised.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/06/2005 **Stopped:** 29/07/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/08/2005	ALT = SGPT		15/08/2004	34	
18/08/2005	ALT = SGPT		29/07/2005	1847	
18/08/2005	ALT = SGPT		02/08/2005	184	
18/08/2005	AST = SGOT		15/08/2004	34	
18/08/2005	AST = SGOT		29/07/2005	1032	
18/08/2005	AST = SGOT		02/08/2005	738	
18/08/2005	GGT = SGGT =	<51	20/08/2004	7	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210925 **Seq:** 1 **Gender:** F
Reported: 18/08/2005 **Weight:** 52.00
Hospitalisation: **Age:** 47
Onset Date: 29/06/2005 **DOB:** 19/07/1957
Outcome: Recovered 11/08/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 15/06/2005 **Stopped:** 29/07/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/08/2005	GGT = SGGT = SGTP	<51	29/07/2005	251	
18/08/2005	SAP = ALP	30-120	20/08/2004	76	
18/08/2005	SAP = ALP	30-120	02/08/2005	184	
18/08/2005	SAP = ALP	30-120	02/08/2005	184	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210926 **Seq:** 1 **Gender:** M
Reported: 18/08/2005 **Weight:** 105.00
Hospitalisation: **Age:** 63
Onset Date: 26/07/2005 **DOB:** 30/01/1942
Outcome: Recovered 27/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, visual	Caused or prolonged inpatient hospitalisation	The patient experienced visual hallucinations overnight and the next morning, was teary and depressed and had a very dry mouth	Septrin withheld on 27/07/2005, then decreased, Endone decreased, then ceased.
Depression	Caused or prolonged inpatient hospitalisation		
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PARACETAMOL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
CLEXANE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
NORVASC (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
TRITACE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 210926 **Seq:** 1 **Gender:** M
Reported: 18/08/2005 **Weight:** 105.00
Hospitalisation: **Age:** 63
Onset Date: 26/07/2005 **DOB:** 30/01/1942
Outcome: Recovered 27/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry mouth	Caused or prolonged inpatient hospitalisation		
Tearfulness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

IKOREL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
PARIET (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
TRANSIDERM-NITRO (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
BETALOC (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Report Detail

Case Number: 210926 **Seq:** 1 **Gender:** M
Reported: 18/08/2005 **Weight:** 105.00
Hospitalisation: **Age:** 63
Onset Date: 26/07/2005 **DOB:** 30/01/1942
Outcome: Recovered 27/07/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

ENDONE (Suspected)			**Reason:** Pain		
Tablet	1.0	Dose Unspecified	As necessary		Oral
Batch:	**Started:** 25/07/2005			**Stopped:**	
SEPTRIN FORTE (Suspected)			**Reason:** Other prophylactic procedures		
Tablet	2.0	Dose Unspecified	Daily		Oral
Batch:	**Started:** 26/07/2005			**Stopped:**	
ZOLOFT (Suspected)			**Reason:**		
Tablet	100.0	Milligram	Daily		Oral
Batch:	**Started:** 22/07/2005			**Stopped:** 26/07/2005	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211021 **Seq:** 1 **Gender:** M
Reported: 24/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Cold sweat Pulmonary oedema		The patient developed cold sweats, rigors with chattering teeth and shivering and fluid build up in the lungs. On the second night he passed out	Cardiac care. Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 2.0 Dose Unspecified Total Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient Medical History: heart attack.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211071 **Seq:** 1 **Gender:** M
Reported: 25/08/2005 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 76
Onset Date: 04/08/2005 **DOB:** 17/06/1929
Outcome: Recovered 15/08/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Life	Patient experienced increasing mental and physical agitation and suicidal ideation leading to psychiatric hospital admission.	Admission. Treated with Benzodiazepine. Ceased Sertraline
Suicidal ideation	Life		

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AVAPRO (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CARTIA (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LIPITOR (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Longstanding mild anxiety and depression - more recent major depression - previously could not tolerate Citalopram or Lexapro.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211071 **Seq:** 1 **Gender:** M
Reported: 25/08/2005 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 76
Onset Date: 04/08/2005 **DOB:** 17/06/1929
Outcome: Recovered 15/08/2005 **Causality:** Causality possible

Reaction Detail

Medicine Details:

TRAMADOL HYDROCHLORIDE (Other drug)			**Reason:**	
Batch:	**Started:**		**Stopped:**	
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression
Tablet	50.0 Milligram	Daily		Oral
Batch:	**Started:**	02/08/2005	**Stopped:**	06/08/2005

Laboratory Investigations:

Additional Information:

History: Longstanding mild anxiety and depression - more recent major depression - previously could not tolerate Citalopram or Lexapro.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211147 **Seq:** 1 **Gender:** F
Reported: 26/08/2005 **Weight:** 48.00
Hospitalisation: **Age:** 79
Onset Date: 15/08/2005 **DOB:** 19/05/1926
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Jaundice	Caused or prolonged inpatient hospitalisation	Patient was severly jaundiced, liver function tests raised, dose of Zoloft was increased to 100mg from 50mg day.	
Liver function test abnormal	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 09/08/2005 **Stopped:** 16/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/08/2005	ALT = SGPT	(<51 U/L)	15/08/2005	452	
26/08/2005	AST = SGOT	(<41 U/L)	15/08/2005	229	
26/08/2005	Bilirubin	(<25 umol/L)	15/08/2005	157	
26/08/2005	GGT = SGGT =	(<51-U/L)	15/08/2005	1155	
26/08/2005	SAP = ALP	(50-140 U/L)	15/08/2005	692	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211156 **Seq:** 1
Reported: 26/08/2005
Hospitalisation:
Onset Date: 22/07/2005
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 40
DOB: 22/12/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Depressed mood Depression Drug ineffective Feeling abnormal Lethargy Mood swings		Patient experienced symptoms when changed from Zoloft to Xydep, within a week of taking Xydep felt not as balanced as they normally are, mood swings, lethargy, sadness, teariness, depression and just a feeling of not being quite right. Similar to how they have felt in the past.	Changed back to Zoloft.

Medicine Details:

Xydep (Suspected) **Reason:**

Batch: **Started:** 17/07/2005 **Stopped:** 17/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211156 **Seq:** 1
Reported: 26/08/2005
Hospitalisation:
Onset Date: 22/07/2005
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 40
DOB: 22/12/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tearfulness			

Medicine Details:

Xydep (Suspected) **Reason:**

Batch: **Started:** 17/07/2005 **Stopped:** 17/08/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211183 **Seq:** 1 **Gender:** F
Reported: 30/08/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Drug therapy changed Nervousness		Patient has been taking Zoloft 100mg for about 10 years. Patient tried Xydep 100mg and experienced anxiety which lasted for a few days. After patient had gone back to Zoloft, anxiety and feeling "shaky" disappeared.	Xydep ceased.

Medicine Details:

Xydep (Suspected) **Reason:**
Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211692 **Seq:** 1
Reported: 15/09/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 29/01/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 39Y
DOB:
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Anxiety Hallucination Insomnia Restlessness		The patient reduced Zoloft dose from 100mg to 50mg without weaning. On the third day she experienced increased anxiety, severe restlessness, 'hypnogogic' hallucinations at night, leading to insomnia and exacerbation of psychosis, leading to suicidality.	Zoloft increased back to [illegible]

Medicine Details:

ZYPREXA (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

LITHICARB (Other drug) **Reason:**
Tablet 750.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 26/01/2004 **Stopped:** 09/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211718 **Seq:** 1
Reported: 16/09/2005
Hospitalisation:
Onset Date: 06/09/2005
Outcome: Not yet recovered

Gender: M
Weight: 71.00
Age: 28
DOB: 25/03/1977
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depressed mood Therapy regimen changed		Changed to Xydep from Zoloft, mood steadily got worse. By day 9, the patientl was quite depressed and very hard to live with (have been on Zoloft for 7 years and have been stable for many years now). returned the Xydep to the Pharmacy and had it swapped for Zoloft and have started taking Zoloft again.	Cease treatment, return to previous SSRI (Zoloft)

Medicine Details:

Xydep (Suspected) **Reason:**

Tablet 250.0 Milligram Daily Oral

Batch: ? **Started:** 06/09/2005 **Stopped:** 15/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211864 **Seq:** 1 **Gender:** M
Reported: 22/09/2005 **Weight:** 0.00
Hospitalisation: **Age:** 74
Onset Date: 15/09/2005 **DOB:** 12/06/1931
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Patient started Zoloft for three months, and experienced tardive dyskinesia.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211893 **Seq:** 1
Reported: 22/09/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 15/11/2004
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 17
DOB: 20/11/1986
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Pateint developed elevated LFT's.	Ceased Risperidone.

Medicine Details:

RISPERIDONE (Suspected) **Reason:** Other atyp forms schizophrenia

Tablet 4.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** 15/03/2004

CARBAMAZEPINE (Suspected) **Reason:**

100.0 Milligram Daily Oral

Batch: **Started:** 15/11/2004 L TERM **Stopped:** 15/02/2005

ZOLOFT (Suspected) **Reason:**

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 211896 **Seq:** 1 **Gender:** F
Reported: 22/09/2005 **Weight:** 60.00
Hospitalisation: **Age:** 38Y
Onset Date: 21/09/2005 **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oesophagitis	Incapacity/disability	oesophagitis after taking Zoloft 100mg with sip of water when cleaning teeth	somac 40mg daily

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 09/10/2003 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient has had this happen before when she takes zoloft at bedtime when cleaning teeth. She usually takes with her evening meal but when she forgets she takes with a sip of water from the tap.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212012 **Seq:** 1
Reported: 27/09/2005
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 18
DOB: 20/11/1986
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aspartate aminotransferase incre Alanine aminotransferase increas		Patient experienced elevate liver function tests with alanine aminotransferase and aspartate aminotransferase.	Risperidone discontinued.

Medicine Details:

RISPERDAL (Suspected) **Reason:** Other atyp forms schizophrenia
4.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 15/03/2005

CARBAMAZEPINE (Suspected) **Reason:**
100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Other atyp forms schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/09/2005	ALT = SGPT				ALT - 160-250.
27/09/2005	AST = SGOT				AST - 70-90.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212024 **Seq:** 1 **Gender:** U
Reported: 28/09/2005 **Weight:** 100.00
Hospitalisation: **Age:** 45
Onset Date: 31/07/2005 **DOB:** 18/09/1959
Outcome: Death, maybe drug 31/07/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Death	Two days after initiation of Zoloft the patient committed suicide by hanging.	
Completed suicide	Death		

Medicine Details:

NEXIUM (Other drug) **Reason:** Other diseases of esophagus
40.0 Milligram
Batch: **Started:** 28/07/2004 **Stopped:**

STILNOX (Other drug) **Reason:** Specific disorders of sleep
10.0 Milligram
Batch: **Started:** 30/05/2005 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 10.0 Milligram Daily Oral
Batch: **Started:** 29/07/2005 **Stopped:** 31/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No prior depressive illness or suicidal behaviour

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212042 **Seq:** 1 **Gender:** F
Reported: 28/09/2005 **Weight:** 0.00
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash	Caused or prolonged inpatient hospitalisation	Patient developed a severe rash where the plaster was. Before starting Zoloft, the consumer did not have any reaction to plasters.	

Medicine Details:

JULIET-35 ED (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ASCORBIC ACID (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 212043 is the second sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212043 **Seq:** 1 **Gender:** F
Reported: 28/09/2005 **Weight:** 0.00
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		The consumer also reported that she used Optislim (herbal, vitamin and mineral) (unspecified) slimming patches for weight loss recently and developed severe rashes over arms and legs.	

Medicine Details:

JULIET-35 ED (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ASCORBIC ACID (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

OPTISLIM 2000 (Suspected) **Reason:** Obesity othr than endoc origin
Batch: **Started:** **Stopped:** 0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 212042 is the first sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212278 **Seq:** 1 **Gender:** F
Reported: 06/10/2005 **Weight:**
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy Premature rupture of membranes		Drug exposure during pregnancy and premature rupture of membranes.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Oral
Batch: **Started:** **Stopped:** Ongoing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient received Zoloft during her pregnancy starting at 14 weeks gestation. Mother is still taking Zoloft while the baby is being breastfed. Baby male born on 04/02/05, weight 3.360kg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212337 **Seq:** 1 **Gender:** F
Reported: 10/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 22
Onset Date: **DOB:** 26/02/1983
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea	Incapacity/disability	The patient developed galactorrhoea and weight gain.	
Weight increased	Incapacity/disability		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

RISPERIDONE (Suspected) **Reason:**
2.0 Milligram Daily
Batch: **Started:** 15/03/2005 **Stopped:** 15/06/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212345 **Seq:** 1 **Gender:** F
Reported: 10/10/2005 **Weight:** 52.00
Hospitalisation: **Age:** 42
Onset Date: 29/01/2005 **DOB:** 03/08/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient received Edronax, (reboxetine), one quarter of a 4mg tablet for two weeks, then	Edronax was ceased and the patient now receives Zoloft

Medicine Details:

EDRONAX (Suspected) **Reason:** Depression
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** 21/01/2005 **Stopped:** 0

ZOLOFT (Suspected) **Reason:** Depression
100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212379 **Seq:** 1
Reported: 11/10/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 20/09/2005
Outcome: Not yet recovered

Gender: F
Weight: 49.50
Age: 40
DOB: 14/07/1965
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Muscle twitching		Patient experienced severe tremors and facial twiching.	

Medicine Details:

Xydep (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 19/09/2005 **Stopped:** 27/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212527 **Seq:** 1 **Gender:** F
Reported: 13/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		When patient developed the seizure, the patient also had two glasses of alcohol.	

Medicine Details:

KARVEA (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SOMAC (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 212547 **Seq:** 1 **Gender:** F
Reported: 13/10/2005 **Weight:** 0.00
Hospitalisation: **Age:** 66
Onset Date: 27/09/2005 **DOB:** 02/11/1938
Outcome: Recovered 13/10/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness	Incapacity/disability	Dizziness, postural hypotension, nausea	
Nausea	Incapacity/disability		
Orthostatic hypotension	Incapacity/disability		

Medicine Details:

Xydep (Suspected) **Reason:**
Tablet 1 time Oral
Batch: **Started:** 27/09/2005 **Stopped:** 13/10/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213248 **Seq:** 1 **Gender:** F
Reported: 09/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia	Incapacity/disability	Patient experienced "severe memory loss" impacting on work.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213381 **Seq:** 1 **Gender:** M
Reported: 14/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 17Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Drug ineffective Overdose		The patient's mood deteriorated and the depressive symptoms relapsed. He felt increasingly frustrated and hopeless. Consequently, he planned and attempted suicide by ingesting a substantial overdose of Pseudoephedrine and Diazepam.	Isotretinoin ceased.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:**

ISOTRETINOIN (Suspected) **Reason:** Other acne of sebaceous glands
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 213377 is the first sequence to this report.
Article title: Acne, Isotretinoin Treatment and Acute Depression.
Article Sorce: World J Biol Psychiatry (2001)2, 159-161.
Article Author: Chee Hong Ng, Mei Mui Tam, Stephen J Hook.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213459 **Seq:** 1 **Gender:** M
Reported: 15/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 19Y
Onset Date: 24/10/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eating disorder	Caused or prolonged inpatient hospitalisation	After ceasing Zoloft, the patient was put on Citalopram for three days. Since 24/10/05, patient has experienced trouble eating ("won't eat") and sleeping ("can't get to sleep")	
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		
Sleep disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Oral
Batch: **Started:** **Stopped:** 24/10/2005

CITALOPRAM HYDROBROMIDE (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213591 **Seq:** 1 **Gender:** F
Reported: 18/11/2005 **Weight:** 60.00
Hospitalisation: Required a visit to the doctor **Age:** 55
Onset Date: 01/09/2005 **DOB:** 03/07/1950
Outcome: Recovered 15/11/2005 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Fatigue Lethargy Muscle tightness		The patient experienced severe diarrhoea, fatigue, tight muscles and was lethargic.	2 courses of Lomotil/gastrolyte tablets needed to control.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 31/08/2005 **Stopped:** 04/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213673 **Seq:** 1 **Gender:** F
Reported: 23/11/2005 **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
Homicidal ideation		The patient experienced homicidal thoughts while taking Zoloft.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Unspecified schizophrenia
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213692 **Seq:** 1 **Gender:** M
Reported: 23/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 23/09/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis Jaundice Pruritus		The patient experienced suspected hepatitis and jaundice with an itch.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 15/10/2005 S TERM **Stopped:** 15/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213702 **Seq:** 1 **Gender:** F
Reported: 23/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Mania Mania		Patient experienced a manic episode after having a surgical procedure (possibl a gynaecological procedure) which involved a general anaesthetic	

Medicine Details:

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213734 **Seq:** 1
Reported: 23/11/2005
Hospitalisation:
Onset Date: 19/11/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 47
DOB: 19/08/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Drug withdrawal syndrome Paraesthesia Vision blurred		The patient experienced a headache, blurred vision, electric shock-like shooting feelings and withdrawal syndrome.	Patient put back on Zoloft 100mg, reducing to 50mg.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** L TERM **Stopped:** 17/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Psychiatrist said this couldn't happen with Zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213738 **Seq:** 1 **Gender:** M
Reported: 24/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: 08/11/2005 **DOB:** 20/02/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	The patient suffered suspected neuroleptic malignant syndrome soon after commencing Clozaril.	Clozaril ceased. Diazepam prescribed for muscle aches and agitation

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 12/10/2005 **Stopped:** 08/11/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2005	Creatine	<241	08/11/2005	105	
24/11/2005	Creatine	<241	09/11/2005	6820	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 213943 **Seq:** 1 **Gender:** F
Reported: 01/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: 18/11/2005 **DOB:** 04/05/1964
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ecchymosis		Patient developed ecchymosis x 10, minimal trauma.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 20/10/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214037 **Seq:** 1
Reported: 06/12/2005
Hospitalisation: Admitted to hospital
Onset Date: 15/07/2005
Outcome: Recovered

Gender: F
Weight: 90.00
Age: 34
DOB: 04/04/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	The patient developed psychotic symptoms and paranoid delusions.	10 x ECT treatments. Zoloft ceased, changed to Quetiapine
Delusion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 1.0 Dose Unspecified Daily Oral

Batch: **Started:** 15/07/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214053 **Seq:** 1 **Gender:** F
Reported: 06/12/2005 **Weight:** 70.00
Hospitalisation: **Age:** 34
Onset Date: 19/05/2003 **DOB:** 18/05/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Apgar score low Drug exposure during pregnancy Fever neonatal Premature rupture of membranes		Baby experienced breathing difficulties, a "slight" temperature, and " the membrance was on his face	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Maternal use of Zolft during pregnancy, reaction in baby

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214101 **Seq:** 1 **Gender:** F
Reported: 08/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: 12/09/2005 **DOB:** 22/05/1953
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypersomnia		The patient experienced excess sleepiness an hour after taking the tablet. She slept for 2.5 hours. The same reaction occurred on rechallenge a few days later.	Ceased Zoloft.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 12/09/2005 **Stopped:** 14/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug rechallenge.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214192 **Seq:** 1 **Gender:** F
Reported: 12/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 04/12/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Agitation Drug withdrawal syndrome		The patient experienced electric shock-like sensations originating in the head and travelling down the limbs. She also experienced agitation, despite a very slow withdrawal period where the dose was decreased by 25mg every 4 weeks.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 04/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214233 **Seq:** 1 **Gender:** F
Reported: 12/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury Akathisia Anger		The patient suddenly could not breathe, her heart was pounding and "the walls seemed to be closing in". The patient thought she was having a heart attack. The nurse told her she was having a panic attack. When a neighbor revved his motorcycle within earshot of her sleeping baby, the patient flew into a rage, chasing him and screaming profanities. That night she used a knife to make shallow cuts in her left forearm, just to see how it felt. She overdosed on sleeping pills, the first of 4 attempts. She developed akathisia.	Nurse placed a paper bag over the patient's mouth. Over time the psychiatrist added tranquilizers, an extra anti-depressant, Lithium and an antipsychotic. Patient had a course of electro convulsive

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214233 **Seq:** 1 **Gender:** F
Reported: 12/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea			
Overdose			
Palpitations			
Panic attack			
Suicide attempt			

Medicine Details:

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214330 **Seq:** 1 **Gender:** F
Reported: 15/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Antinuclear antibody increased	Caused or prolonged inpatient hospitalisation	The patient experienced gastro-intestinal problems and has raised antinuclear antibodies	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 15/11/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214378 **Seq:** 1 **Gender:** F
Reported: 16/12/2005 **Weight:** 0.00
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Deafness neurosensory	Incapacity/disability	About six months after starting Zoloft, the patient started to lose her hearing, the patient has lost 50% of her hearing in both ears	

Medicine Details:

ETHINYLOESTRADIOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LEVONORGESTREL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis
Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214406 **Seq:** 1 **Gender:** F
Reported: 19/12/2005 **Weight:** 60.00
Hospitalisation: **Age:** 40Y
Onset Date: 21/10/2005 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chest pain	Incapacity/disability	The patient experienced a headache and a central chest pain, radiating up to the jaw which lasted a few hours.	Zoloft ceased.
Headache	Incapacity/disability		
Pain in jaw	Incapacity/disability		

Medicine Details:

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

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 21/10/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214521 **Seq:** 1 **Gender:** M
Reported: 03/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 26
Onset Date: **DOB:** 14/06/1979
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation Akathisia Automatism Delirium Suicide attempt		The patient experienced neuroleptic-induced akathisia with serious restlessness, homicidal ideation and possibly 20 suicide attempts, non-insane automatism, delirium, toxic psychosis and movement disorder.	Zoloft to be ceased slowly.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 15/04/1998 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214517 is the first sequence to this report.
Been off medication for only two months during 2001 or 2002. He recalled being very depressed, with suicidal ideation but during this period he was not inclined to act on these urges.
Patient must not have Chlorpromazine or Haloperidol as he had developed painful tormenting akathisia on these before.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214522 **Seq:** 1 **Gender:** F
Reported: 03/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 14/03/1953
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania Delirium		The patient experienced manic switch whilst on Zoloft, and ended up delirious in the backyard of her colleague.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 15/05/2002 **Stopped:** 15/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214535 **Seq:** 1 **Gender:** F
Reported: 03/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 21/02/1950
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		When the patient ceases Zoloft "she gets really bad, very,very agitated, very angry". She has headaches and somatic complaints in her arms, back, neck and legs. She is irritable, not sleeping, can be sad, very depressed and worried. She says when it gets really bad, she gets dizzy and nauseated and has to lie down. She has panic attacks, has gained weight and lacks memory. She also has gynaecological problems which could be a prolapse of the bowel or a fistula	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214544 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 16/05/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	The patient made three suicide attempts whilst on Zoloft.	Zoloft ceased, changed to
Akathisia	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214545 is the second sequence to this report and report 214546 is the third sequence.

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214544 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 16/05/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

Report 214545 is the second sequence to this report and report 214546 is the third sequence.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214571 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: **DOB:** 26/02/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Akathisia Automatism Confusional state Insomnia Suicide attempt		The patient felt like a zombie, had suicidal thoughts, was unable to sleep much, couldn't concentrate, had erratic thought patterns and non-insane automatism. He was agitated and lost a lot of weight.	

Medicine Details:

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

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214578 **Seq:** 1 **Gender:** M
Reported: 04/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 16/02/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Akathisia Suicide attempt		The patient was on Zoloft for a month. It had no effect, but he drank and then he became obsessively suicidal and had violent thoughts. He attempted suicide. He was also agitated, sleepless and paced a lot.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
Oral Liquid 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214653 **Seq:** 1
Reported: 06/01/2006
Hospitalisation: Admitted to hospital
Onset Date: 15/11/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 50Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia	Caused or prolonged inpatient hospitalisation	The patient developed menorrhagia.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 01/11/2005 **Stopped:** 20/11/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214654 **Seq:** 1
Reported: 06/01/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 66Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	The patient developed suspected serotonin syndrome.	Zoloft ceased.

Medicine Details:

ENDEP (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 10/10/2000 **Stopped:** 16/10/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had occurred previously whilst using Cipramil.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214860 **Seq:** 1
Reported: 11/01/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 11/12/2005
Outcome: Unknown

Gender: F
Weight: 120.00
Age: 41
DOB: 25/04/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Patient developed a drug withdrawal	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 15/04/2004 **Stopped:** 09/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214864 is the second sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214864 **Seq:** 1
Reported: 11/01/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 13/12/2005
Outcome: Recovered

Gender: F
Weight: 120.00
Age: 41
DOB: 25/04/1964
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Onset of symptoms - shakes, dizziness, panicky feelings and depression within 3 to 4 days. Symptoms eased/recovering on resumption of Zoloft brand tabs.	Changed back to Zoloft.

Medicine Details:

Sertraline-DP 100 (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 09/12/2005 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214860 is the first sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 214877 **Seq:** 1 **Gender:** F
Reported: 11/01/2006 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 14
Onset Date: 27/12/2005 **DOB:** 15/05/1991
Outcome: Recovered 28/12/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	Patient attempted suicide by overdose.	
Overdose	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 18/12/2005 **Stopped:** 28/12/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215158 **Seq:** 1 **Gender:** F
Reported: 23/01/2006 **Weight:** 101.00
Hospitalisation: Required a visit to the doctor **Age:** 57
Onset Date: 01/11/2005 **DOB:** 23/01/1948
Outcome: Recovered 05/11/2005 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Burning sensation Diarrhoea Dry mouth Nausea Palpitations		The patient experienced anxiety, was unable to eat, felt nauseous, had heart palpitations, burning sensation in arms, a dry mouth and some diarrhoea	

Medicine Details:

BRUFEN (Other drug) **Reason:** Unspecified arthritis
Batch: **Started:** **Stopped:**

Glucosamine Nos (Other drug) **Reason:** Unspecified arthritis
Batch: **Started:** **Stopped:**

STILNOX (Other drug) **Reason:** Specific disorders of sleep
Batch: **Started:** **Stopped:**

ZANTAC (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215158 **Seq:** 1
Reported: 23/01/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 01/11/2005
Outcome: Recovered 05/11/2005

Gender: F
Weight: 101.00
Age: 57
DOB: 23/01/1948
Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected) **Reason:** Menopausal symptoms

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 19/10/2005 S TERM **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215216 **Seq:** 1 **Gender:** F
Reported: 24/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased		The patient complained of low libido whilst taking Zoloft.	Zoloft ceased, changed to

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 215218 is the second sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215312 **Seq:** 1 **Gender:** U
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 20/08/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Headache Amnesia Disturbance in attention Formication		The patient experienced headaches, was suicidal and had concentration and memory problems. She was 'hyper' and had racing thoughts	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215315 **Seq:** 1 **Gender:** M
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 20/08/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cognitive disorder Akathisia Amnesia		The patient became impaired cognitively, has memory and concentration problems, felt inner restlessness, has an inability to keep still, is fidgety, cannot keep his legs still, has a feeling of tension and complained of clenching his teeth. He felt general unease and irritability. On a high dose of Zoloft he was jittery, had aggressive thoughts, couldn't think much at all, was very tired, had suicidal thoughts, poor concentration and memory and sleep difficulty. He had feelings of being angry and was agitated.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215315 **Seq:** 1 **Gender:** M
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 20/08/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 25.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215338 **Seq:** 1 **Gender:** F
Reported: 27/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 27Y
Onset Date: 19/01/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous	Incapacity/disability	erythematus rash on legs, arms and back	calamine lotion

Medicine Details:

Yasmin (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram 1 time Oral
Batch: **Started:** 05/01/2006 **Stopped:** 20/01/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215363 **Seq:** 1 **Gender:** M
Reported: 30/01/2006 **Weight:** 0.00
Hospitalisation: **Age:** 24
Onset Date: **DOB:** 11/03/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased Aggression Akathisia Restlessness Suicidal ideation		The patient complained that it was hard to ejaculate and he had less sexual desire, felt restless, was sometimes a little agitated and had violent thoughts, was easily irritated, had thoughts of killing himself, had racing thoughts, had akathisia, experienced obsessionality, list making, video replay and poor sleep.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

CANNABIS PREPARATION (Suspected) **Reason:**
3.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215629 **Seq:** 1
Reported: 07/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 30/01/2006
Outcome: Recovered

Gender: M
Weight: 57.00
Age: 50
DOB: 04/02/1955
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pharyngolaryngeal pain	Caused or prolonged inpatient hospitalisation	The patient experienced burning in the throat, sweatiness and a hoarse voice 5 minutes after taking his first dose of Xydep.	
Dysphonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Xydep (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 30/01/2006 **Stopped:** 30/01/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug timing certain.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215713 **Seq:** 1
Reported: 10/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 05/01/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 06/09/1932
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Patient developed serotonin syndrome, motor restlessness and shivering.	Edronax, Avanza and Zoloft
Akathisia	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATENOLOL (Other drug) **Reason:**
Tablet 25.0 Milligram Oral
Batch: **Started:** **Stopped:**

SOMAC (Other drug) **Reason:**
40.0 Milligram
Batch: **Started:** **Stopped:**

COVERSYL (Other drug) **Reason:**
Tablet 8.0 Milligram Oral
Batch: **Started:** **Stopped:** 03/01/2006

COLOXYL (Other drug) **Reason:**
120.0 Milligram
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Endep recently ceased (prior to 28/12/05). Patient also has anorexia nervosa and SIADH.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215713 **Seq:** 1
Reported: 10/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 05/01/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 06/09/1932
Causality: Causality possible

Reaction Detail

Medicine Details:

ZYPREXA (Other drug)			**Reason:**			
	10.0	Milligram	As necessary			
Batch:	**Started:**			**Stopped:**	01/01/2006	Ceased
ANTENEX (Suspected)			**Reason:**	Anxiety neurosis		
Tablet	10.0	Milligram	As necessary	Oral		
Batch:	**Started:**			**Stopped:**		0
ZOLOFT (Suspected)			**Reason:**	Anxiety neurosis		
Tablet	150.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**		
AVANZA (Suspected)			**Reason:**	Depression		
Tablet	30.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**		

Laboratory Investigations:

Additional Information:
Endep recently ceased (prior to 28/12/05). Patient also has anorexia nervosa and SIADH.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215713 **Seq:** 1
Reported: 10/02/2006
Hospitalisation: Admitted to hospital
Onset Date: 05/01/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 73
DOB: 06/09/1932
Causality: Causality possible

Reaction Detail

Medicine Details:

EDRONAX (Suspected)				**Reason:**	
Tablet	4.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:
Endep recently ceased (prior to 28/12/05). Patient also has anorexia nervosa and SIADH.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 215900 **Seq:** 1 **Gender:** F
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: **Age:** 32Y
Onset Date: 03/02/2006 **DOB:**
Outcome: Recovered 04/02/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Dizziness Hypoaesthesia Lethargy		The patient felt sick, dizzy, lethargic and experienced numbness over the whole body, especially the arms after each of two doses of Xydep.	Xydep ceased, changed back to Zoloft.

Medicine Details:

Xydep (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 03/02/2006 **Stopped:** 04/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216094 **Seq:** 1 **Gender:** F
Reported: 22/02/2006 **Weight:** 77.00
Hospitalisation: **Age:** 44
Onset Date: 05/02/2006 **DOB:** 15/08/1961
Outcome: Recovered 15/02/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise Liver function test abnormal Nausea		Patient experienced malaise, nausea, [illegible] LFT	

Medicine Details:

Nicobrevin (Suspected) **Reason:** Smoker
Batch: **Started:** 17/01/2006 **Stopped:** 05/02/2006

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216129 **Seq:** 1 **Gender:** F
Reported: 24/02/2006 **Weight:** 0.00
Hospitalisation: **Age:** 54Y
Onset Date: 09/01/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coronary artery occlusion Circulatory collapse		The patient's heart symptoms worsened whilst on Zoloft and she collapsed and was taken to hospital where artery blockage was diagnosed	"Stent" inserted. Zoloft ceased.

Medicine Details:

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

Tablet 25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216181 **Seq:** 1 **Gender:** F
Reported: 27/02/2006 **Weight:** 66.00
Hospitalisation: **Age:** 26Y
Onset Date: 14/02/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Life	I am reporting an adverse reaction I experienced myself. I have taken Zoloft, 150mg daily, for six years and am very familiar with its effects. I was advised that the generic brand sertraline, from the "DP" company was exactly the same. Before swapping from Zoloft to the DP sertraline I was emotionally stable and physically healthy. However, after about six days on the new drug I became increasingly dizzy, anxious, depressed, experienced restless legs and general agitation, uncontrollable crying and eventually became suicidal. At this point I went back to the Zoloft and was fine within days. I spoke to a friend about it, and she said she had tried the same thing, and had also gone off it ...	Return to Zoloft brand

Medicine Details:

Sertraline-DP 100 (Suspected) **Reason:**

Capsule 150.0 Milligram Daily Oral

Batch: **Started:** 09/02/2006 **Stopped:** 17/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216181 **Seq:** 1 **Gender:** F
Reported: 27/02/2006 **Weight:** 66.00
Hospitalisation: **Age:** 26Y
Onset Date: 14/02/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
		... quickly because her mood deteriorated rapidly. I double checked that the dosage was correct. I don't think these generic drugs should be supplied in place of existing drugs if they are not absolutely identical	

Medicine Details:

Sertraline-DP 100 (Suspected) **Reason:**
Capsule 150.0 Milligram Daily Oral
Batch: **Started:** 09/02/2006 **Stopped:** 17/02/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216336 **Seq:** 1 **Gender:** F
Reported: 08/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 66Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Caused or prolonged inpatient hospitalisation	Patient experienced profound ataxia, noted weakness on one side, found to have a soft palate dysfunction with dysphagia,	
Dysphagia	Caused or prolonged inpatient hospitalisation		
Hemiparesis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 216336 **Seq:** 1 **Gender:** F
Reported: 08/03/2006 **Weight:** 0.00
Hospitalisation: **Age:** 66Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palatal disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AVANZA (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216461 **Seq:** 1
Reported: 13/03/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 03/03/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 75
DOB: 19/01/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Asthenia Confusional state Hypokalaemia Vomiting		Severe hyponatraemia/hypokalaemia leading to confusion, weakness, vomiting and peripherally shutdown.	

Medicine Details:

WARFARIN SODIUM (Other drug) **Reason:**
5.0 Milligram
Batch: **Started:** **Stopped:**

XALATAN (Other drug) **Reason:** Unspecified glaucoma
Eye Drops
Batch: **Started:** **Stopped:**

LIPITOR (Other drug) **Reason:** Othr&unspec metabolic diseases
10.0 Milligram Daily
Batch: **Started:** **Stopped:**

LUCRIN DEPOT (Other drug) **Reason:** Malignant neoplasm of prostate
22.0 Milligram Daily Intravenous
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had previously been on zoloft 6 years before dose 50mg daily but not in combination with coversyl plus.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216461 **Seq:** 1
Reported: 13/03/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 03/03/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 75
DOB: 19/01/1931
Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)		**Reason:**	Anxiety neurosis
	100.0 Milligram Daily		
Batch:	**Started:** 20/02/2006	**Stopped:**	01/03/2006
COVERSYL PLUS (Suspected)		**Reason:**	Essential benign hypertension
	1.0 Dose Unspecified Daily		
Batch:	**Started:**	**Stopped:**	04/03/2006

Laboratory Investigations:

Additional Information:
Had previously been on zoloft 6 years before dose 50mg daily but not in combination with coversyl plus.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216542 **Seq:** 1
Reported: 16/03/2006
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
Convulsion Dry mouth Headache		Patient reports that the headaches are increasingly becoming a problem. He will wake up with a headache and it will not go until evening. The patient stated that he always had headaches but Zoloft increased them. He also experienced dry mouth, facial rash and reported that he cannot got out in the sun as the sun irritates his headaches, as if the brain is sizzling, tingling in the feet and hands and nausea. He also experienced seizures that are described as "aura tingling face and or feet, biting tongue, eyes rolling to the back of	

Medicine Details:

TRITACE (Other drug) **Reason:**

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

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 15/07/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216542 **Seq:** 1
Reported: 16/03/2006
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
Nausea Paraesthesia Photosensitivity reaction Rash Therapy regimen changed			

Medicine Details:

TRITACE (Other drug) **Reason:**

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

ZOLOFT (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 15/07/2005 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216648 **Seq:** 1
Reported: 23/03/2006
Hospitalisation: Admitted to hospital
Onset Date: 18/02/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 86Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation	Patient developed raised liver function tests-hepatitis.	
Hepatitis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FRUSEMIDE (Other drug) **Reason:**
20.0 Milligram Oral
Batch: **Started:** **Stopped:**

RIVASTIGMINE (Other drug) **Reason:** Unspecified psychosis
9.0 Milligram Oral
Batch: **Started:** **Stopped:**

FERROUS SULPHATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/03/2006	ALT = SGPT	<55	17/02/2006	2123	
23/03/2006	ALT = SGPT	<55	19/02/2006	782	
23/03/2006	ALT = SGPT	<55	20/02/2006	371	
23/03/2006	ALT = SGPT	<55	21/02/2008	187	
23/03/2006	AST = SGOT	5-50	17/02/2006	1785	
23/03/2006	AST = SGOT	5-50	18/02/2006	756	
23/03/2006	AST = SGOT	5-50	21/02/2008	27	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216648 **Seq:** 1
Reported: 23/03/2006
Hospitalisation: Admitted to hospital
Onset Date: 18/02/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 86Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PARACETAMOL (Suspected)			**Reason:**	Pain	
	4.0	Gram	Daily		Oral
Batch:	**Started:**			**Stopped:**	18/02/2006
ATORVASTATIN (Suspected)			**Reason:**	Othr&unspec metabolic diseases	
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	18/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/03/2006	AST = SGOT	5-50	19/02/2006	199	
23/03/2006	Bilirubin	2-20	17/02/2006	25	
23/03/2006	Bilirubin	2-20	19/02/2006	16	
23/03/2006	Bilirubin	2-20	20/02/2006	12	
23/03/2006	Bilirubin	2-20	21/02/2006	11	
23/03/2006	GGT = SGGT =	12-43	17/02/2006	505	
23/03/2006	GGT = SGGT =	12-43	19/02/2006	329	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216648 **Seq:** 1
Reported: 23/03/2006
Hospitalisation: Admitted to hospital
Onset Date: 18/02/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 86Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

FRUSEMIDE (Other drug)			**Reason:**		
	20.0	Milligram			Oral
Batch:	**Started:**			**Stopped:**	
RIVASTIGMINE (Other drug)			**Reason:**	Unspecified psychosis	
	9.0	Milligram			Oral
Batch:	**Started:**			**Stopped:**	
FERROUS SULPHATE (Other drug)			**Reason:**		
Batch:	**Started:**			**Stopped:**	
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/03/2006	GGT = SGGT = [illegible]	12-43	21/02/2008	221	
23/03/2006	GGT = SGGT = [illegible]	12-43	20/02/2006	259	
23/03/2006	LDH	125-240	17/02/2006	2159	
23/03/2006	LDH	125-240	18/02/2006	583	
23/03/2006	LDH	125-240	19/02/2006	248	
23/03/2006	LDH	125-240	21/02/2008	202	
23/03/2006	SAP = ALP	20-110	17/02/2006	301	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216648 **Seq:** 1
Reported: 23/03/2006
Hospitalisation: Admitted to hospital
Onset Date: 18/02/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 86Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

PARACETAMOL (Suspected)			**Reason:**	Pain	
	4.0	Gram	Daily		Oral
Batch:	**Started:**			**Stopped:**	18/02/2006
ATORVASTATIN (Suspected)			**Reason:**	Othr&unspec metabolic diseases	
Tablet	20.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	18/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/03/2006	SAP = ALP	20-110	19/02/2006	208	
23/03/2006	SAP = ALP	20-110	20/02/2006	175	
23/03/2006	SAP = ALP	20-110	21/02/2008	152	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216789 **Seq:** 1
Reported: 29/03/2006
Hospitalisation: Admitted to hospital
Onset Date: 01/09/2005
Outcome: Not yet recovered

Gender: M
Weight: 106.00
Age: 74
DOB: 26/04/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush	Caused or prolonged inpatient hospitalisation	Patient presented with hot fluhes, tingling in the legs, falls racing heart, shortness of breath, dyskinetic movements, developed postural hypotension	Serotoninergic
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SIMVASTATIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

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

OMEPRAZOLE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ATENOLOL (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216789 **Seq:** 1
Reported: 29/03/2006
Hospitalisation: Admitted to hospital
Onset Date: 01/09/2005
Outcome: Not yet recovered

Gender: M
Weight: 106.00
Age: 74
DOB: 26/04/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		
Paraesthesia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMIODARONE HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ALLOPURINOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

AMITRIPTYLINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216842 **Seq:** 1 **Gender:** U
Reported: 31/03/2006 **Weight:** 60.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 26/03/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Patient experienced depression after starting Horseradish.	Ceased Horseradish.

Medicine Details:

ZOLOFT (Interaction) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

HORSERADISH (Interaction) **Reason:**
3.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216969 **Seq:** 1 **Gender:** F
Reported: 04/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 51
Onset Date: **DOB:** 29/03/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient had a seizure following zoloft increase from 50mg to 100mg daily.	Zoloft ceased.
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 03/01/2006 **Stopped:** 01/02/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 216980 **Seq:** 1 **Gender:** U
Reported: 04/04/2006 **Weight:** 55.00
Hospitalisation: Required a visit to the doctor **Age:** 30
Onset Date: 21/02/2006 **DOB:** 15/10/1975
Outcome: Recovered 25/02/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Anxiety		Extreme agitation and anxiety on previously well tolerated drug.	Withdrawal of Zoloft.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 02/02/2006 **Stopped:** 23/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previously no problems with Zoloft in past.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217646 **Seq:** 1 **Gender:** U
Reported: 24/04/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blindness		Patient experienced temporary loss of	

Medicine Details:

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217649 **Seq:** 1 **Gender:** F
Reported: 24/04/2006 **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 ineffective	Caused or prolonged inpatient hospitalisation	Patient experienced a lack of effect while being treated with Abilify.	5 months in an acute

Medicine Details:

ZOLOFT (Suspected)				**Reason:**	
Tablet					Oral
Batch:	**Started:**			**Stopped:**	
CLOZAPINE (Suspected)				**Reason:**	
Tablet					Oral
Batch:	**Started:**			**Stopped:**	
Abilify (Suspected)				**Reason:**	Unspecified schizophrenia
Tablet	30.0	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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217679 **Seq:** 1 **Gender:** F
Reported: 25/04/2006 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 32Y
Onset Date: 03/04/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence Anxiety Asthenia Burning sensation Dizziness Nausea		severe drowsiness, weakness, dizziness, feeling faint, painful burning sensations in arms and chest, nausea and anxiety.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 04/03/2006 **Stopped:** 04/05/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217698 **Seq:** 1
Reported: 26/04/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Caused or prolonged inpatient hospitalisation	Patient suffered severe diarrhoea.	Zoloft withdrawn.

Medicine Details:

CORTICOSTEROID NOS (Other drug)			**Reason:**		
Batch:	**Started:**			**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	100.0	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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217814 **Seq:** 1 **Gender:** F
Reported: 01/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 30Y
Onset Date: 01/01/1990 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Events occurred in late 1980s or early 1990s

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217815 **Seq:** 1 **Gender:** F
Reported: 01/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident Cyanosis Dizziness		Patient is feeling giddy. Also reports that she has experienced numerous strokes on unknown dates and that her hands go blue on the inside but not on the outside.	

Medicine Details:

PANADOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217865 **Seq:** 1 **Gender:** M
Reported: 02/05/2006 **Weight:** 74.00
Hospitalisation: **Age:** 22
Onset Date: 06/04/2006 **DOB:** 23/11/1983
Outcome: Recovered with sequelae 08/04/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tonic convulsion	Life	Experienced syncopal event with observed tonic activity the day after discharge after an overnight stay for EUA arthroscopy to his L shoulder	seizure terminated spontaneously. Required admission to hospital for 2 nights. Medications withdrawn. EEG, CT brain normal
Drug interaction	Life		
Hypertonia	Life		
Syncope	Life		

Medicine Details:

ZOLOFT (Interaction) **Reason:** Depression
Oral
Batch: **Started:** **Stopped:** 0

TRAMAL SR (Interaction) **Reason:** Other disturbance of sensation
Capsule 200.0 Milligram Daily Oral
Batch: **Started:** 04/04/2006 **Stopped:** 0

CAPADEX (Other drug) **Reason:** Other disturbance of sensation
Capsule 2.0 4 times Oral
Batch: **Started:** 04/04/2006 **Stopped:**

Diclohexal (Other drug) **Reason:** Other disturbance of sensation
Tablet 150.0 Milligram 3 times Oral
Batch: **Started:** 04/04/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217873 **Seq:** 1
Reported: 02/05/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 01/04/2006
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 15
DOB: 04/02/1991
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne		2/52 after starting Zoloft patient developed facial acne (vulgaris).	Differinand Benzoyl Perozxide.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 14/03/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217904 **Seq:** 1 **Gender:** F
Reported: 02/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 82
Onset Date: 15/01/2006 **DOB:** 14/02/1923
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancytopenia Hairy cell leukaemia Mental disorder		Patient developed Pancytopenia, hairy cell leukemia and decreased mental state.	Risperdal discontinued.

Medicine Details:

RISPERDAL (Suspected) **Reason:**
1.0 Milligram Oral
Batch: **Started:** **Stopped:** 03/02/2006 0

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

METFORMIN HYDROCHLORIDE (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/05/2006	Bone marrow				Bone marrow aspirate showed hairy cell leukemia

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 217953 **Seq:** 1
Reported: 03/05/2006
Hospitalisation: Admitted to hospital
Onset Date: 08/02/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 53
DOB: 19/09/1951
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Caused or prolonged inpatient hospitalisation	Patient developed pancreatitis and was	Patient was moved on to
Blood amylase increased	Caused or prolonged inpatient hospitalisation		
Chest pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 28/10/2004 **Stopped:** 08/02/2005 0

ZOCOR (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 08/02/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/05/2006	Amylase				1888 (188?)

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218159 **Seq:** 1 **Gender:** F
Reported: 09/05/2006 **Weight:** 55.00
Hospitalisation: **Age:** 28
Onset Date: 23/04/2006 **DOB:** 25/01/1978
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Formication Rhinitis		Widespread itching, formication severe allergic rhinitis, no visible rash.	Drug withdrawn, symptoms recurred on ingestion of Citalopram

Medicine Details:

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

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 13/01/2006 **Stopped:** 24/04/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 218166 is the second sequence to this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218217 **Seq:** 1
Reported: 10/05/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 02/02/2006
Outcome: Recovered

Gender: U
Weight: 55.00
Age: 51
DOB: 14/08/1954
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Patient developed rash across neck and decolletage, (macropapular).	

Medicine Details:

KALMA (Other drug) **Reason:** Chronic sinusitis
Tablet 30.0 Milligram As necessary Oral
Batch: **Started:** L TERM **Stopped:**

KALMA (Other drug) **Reason:** Anxiety neurosis
Tablet 3.0 Milligram Daily Oral
Batch: **Started:** 15/12/2005 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Batch: **Started:** 27/01/2006 **Stopped:** 05/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218436 **Seq:** 1 **Gender:** F
Reported: 17/05/2006 **Weight:** 70.00
Hospitalisation: **Age:** 31
Onset Date: 15/03/2006 **DOB:** 06/02/1975
Outcome: Recovered 04/05/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Drug ineffective Drug withdrawal syndrome		Patient was on Zoloft, went to different chemist and got Xydep, experienced withdrawal symptoms within 24 hours, and over next 3 weeks went backwards in her depression.	Went back on Zoloft.

Medicine Details:

Xydep (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 15/03/2006 **Stopped:** 15/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218439 **Seq:** 1 **Gender:** M
Reported: 17/05/2006 **Weight:** 90.00
Hospitalisation: Admitted to hospital **Age:** 90
Onset Date: 18/01/2006 **DOB:** 01/01/1916
Outcome: Recovered 02/02/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient developed neutropenia.	

Medicine Details:

PARIET (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

THIAMINE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MULTIVITAMINS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DIAMICRON (Other drug) **Reason:** Diabetes mellitus
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/05/2006	Neutrophils		18/01/2006	1.1	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218439 **Seq:** 1 **Gender:** M
Reported: 17/05/2006 **Weight:** 90.00
Hospitalisation: Admitted to hospital **Age:** 90
Onset Date: 18/01/2006 **DOB:** 01/01/1916
Outcome: Recovered 02/02/2006 **Causality:** Causality probable

Reaction Detail

Medicine Details:

PREDNISONE (Other drug)		**Reason:**	Gout
Batch:	**Started:**		**Stopped:**
COLOXYL WITH SENNA (Other drug)		**Reason:**	Constipation
Batch:	**Started:**		**Stopped:**
AGAROL (Other drug)		**Reason:**	Constipation
Batch:	**Started:**		**Stopped:** 0
ZOLOFT (Suspected)		**Reason:**	Depression
Tablet	25.0 Milligram	Daily	Oral
Batch:	**Started:** 16/01/2006		**Stopped:** 18/01/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218458 **Seq:** 1
Reported: 18/05/2006
Hospitalisation: Required a specialist consultation
Onset Date: 15/03/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 56Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia Liver function test abnormal		Patient commenced Alendronate Sodium tablets together with Sertraline HCl and Ergocalciferol. On that day and for the next two days, patient experienced terrible heartburn and liver function test raised.	Valium stopped.

Medicine Details:

COVERSYL PLUS (Other drug) **Reason:** Essential benign hypertension
Tablet Oral
Batch: **Started:** 01/01/2002 L TERM **Stopped:** Continued.

TEMAZEPAM (Other drug) **Reason:** Depression
Oral
Batch: **Started:** 01/01/1986 L TERM **Stopped:** 01/01/2004

VALIUM (Suspected) **Reason:** Depression
Batch: **Started:** 01/01/2005 **Stopped:** 0

OSTELIN 1000 (Suspected) **Reason:**
Capsule Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of Temazepam overdose and a family history of dementia and depression for more than 20 years.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218458 **Seq:** 1
Reported: 18/05/2006
Hospitalisation: Required a specialist consultation
Onset Date: 15/03/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 56Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

FOSAMAX ONCE WEEKLY TABLETS (Suspected)			**Reason:** Osteoporosis		
Tablet	70.0	Milligram	Weekly		Oral
Batch:	**Started:** 15/04/1999	L TERM	**Stopped:**		
ZOLOFT (Suspected)			**Reason:** Depression		
Tablet	1.0	Dose Unspecified	Daily		Oral
Batch:	**Started:** 01/01/2005		**Stopped:**		

Laboratory Investigations:

Additional Information:
History of Temazepam overdose and a family history of dementia and depression for more than 20 years.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218573 **Seq:** 1
Reported: 23/05/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 80.00
Age: 31
DOB: 01/11/1974
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Depression		On Sertraline and got Xydep brand and felt bad despite going up to 1.5 tablets each day. Depression worsening.	Recommended back to Zoloft

Medicine Details:

Xydep (Suspected) **Reason:**

Tablet 150.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218630 **Seq:** 1 **Gender:** F
Reported: 23/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Drug ineffective		Patient felt unwell, felt as though symptoms were returning. Did not feel as though it works as well as Zoloft.	Ceased GenRx Sertraline.

Medicine Details:

GenRx Sertraline (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 10/05/2006 **Stopped:** 12/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218731 **Seq:** 1 **Gender:** F
Reported: 29/05/2006 **Weight:** 70.00
Hospitalisation: **Age:** 59
Onset Date: 10/04/2006 **DOB:** 23/12/1946
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Pruritus		Rash - scalp itch, body rash and internal	Zoloft ceased.

Medicine Details:

NORVASC (Other drug) **Reason:** Essential benign hypertension
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 03/04/2006 **Stopped:** 14/04/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218738 **Seq:** 1 **Gender:** U
Reported: 29/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthma Bronchospasm		Pateint has developed bronchospasm and worsening of asthma symptoms.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218826 **Seq:** 1 **Gender:** F
Reported: 31/05/2006 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: 29/05/2006 **DOB:** 27/07/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Had low sodium levels (123) and low potassium levels (2.0) which is probably due to vomiting of preganancy but medical staff thought SIADH from Zoloft may be contributing. She has been on the Zoloft at least since 2004.	Corrected with IV fluids, changed from Zoloft to Efexor.
Hypokalaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 218839 **Seq:** 1 **Gender:** F
Reported: 01/06/2006 **Weight:** 75.00
Hospitalisation: **Age:** 23
Onset Date: **DOB:** 03/08/1982
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient has been on Zoloft for approximately one week and had a small [illegible]	Zoloft was discontinued.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Patient had sustained a serious head injury previously.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219003 **Seq:** 1
Reported: 06/06/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 87
DOB: 08/02/1919
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Suspected serotonin syndrome.	Zoloft and Tramal ceased. Patient currently on Mirtazapine

Medicine Details:

ZOLOFT (Interaction) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 04/04/2006 **Stopped:** 13/04/2006 0

TRAMAL (Interaction) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 15/05/2005 **Stopped:** 13/04/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of arthritis, hypertension, hemiplegia-polio, pulmonary fibrosis and hypothyroidism. Also taking Endep.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219057 **Seq:** 1
Reported: 07/06/2006
Hospitalisation: Admitted to hospital
Onset Date: 03/02/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 74
DOB: 13/07/1931
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Admitted to cardiac ward with syncope and hyponatraemia. Sertraline 50mg was increased to 100mg.	Sertraline ceased. Synacthen test negative-other tests negative
Hyponatraemia	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 16/01/2006 **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 30/01/2006 **Stopped:** 02/02/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219206 **Seq:** 1
Reported: 19/06/2006
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Recovered

Gender: F
Weight: 56.00
Age: 47
DOB: 30/11/1958
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome		Restless legs - discomfort in knees and needing to move legs around after sitting or lying for long periods. Started after about 6 months on Zoloft	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 11/06/2004 **Stopped:** 15/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219249 **Seq:** 1
Reported: 19/06/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 15/11/2005
Outcome: Not yet recovered

Gender: M
Weight: 101.60
Age: 34
DOB: 27/02/1971
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Drug therapy changed		Failure of medication when generic brand was used. Changed from Zoloft 100mg to Eleva 100mg	Patient changed back to Zoloft.

Medicine Details:

RISPERDAL (Other drug) **Reason:** Otr spec symp psychopathol nec
2.0 Milligram Daily
Batch: **Started:** 01/01/2000 **Stopped:**

Eleva 100 (Suspected) **Reason:**
Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219310 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 65.00
Hospitalisation: Required a visit to the doctor **Age:** 15
Onset Date: 27/01/2006 **DOB:** 08/10/1990
Outcome: Recovered 07/06/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia Alopecia		Hair loss - alopecia generalised.	

Medicine Details:

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

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 19/09/2005 **Stopped:** 13/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219328 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 70.00
Hospitalisation: **Age:** 59
Onset Date: **DOB:** 01/07/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination, visual Therapy regimen changed		Colourful visual hallucinations which go in 1/2 hours or so and don't bother her. Increased Zoloft dose last 6/12.	

Medicine Details:

INDERAL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

LIPEX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

NATRILIX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

NEXIUM (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219328 **Seq:** 1 **Gender:** F
Reported: 20/06/2006 **Weight:** 70.00
Hospitalisation: **Age:** 59
Onset Date: **DOB:** 01/07/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Medicine Details:

PANADEINE FORTE (Other drug)			**Reason:**	
Batch:	**Started:**		**Stopped:**	
ALEPAM (Other drug)			**Reason:**	
Tablet	7.5 Milligram		As necessary	Oral
Batch:	**Started:**	L TERM	**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	
Tablet				Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219723 **Seq:** 1 **Gender:** F
Reported: 05/07/2006 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 47
Onset Date: 29/12/2005 **DOB:** 14/08/1958
Outcome: Recovered with sequelae 11/01/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delusional disorder, persecutory	Life	Developed paranoid psychosis -	
Homicidal ideation	Life	Homicidal attempt - stabbed her daughter in the belief that there was a conspiracy to kill her	Locked psychiatric ward for 2 weeks. Sedation & observation.
Post-traumatic stress disorder	Life		

Medicine Details:

DI-GESIC (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 29/12/2005

LOMOTIL (Suspected) **Reason:** Diarrhea
Oral
Batch: **Started:** 28/12/2005 **Stopped:** 29/12/2005

DIAZEPAM (Suspected) **Reason:** Anxiety neurosis
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 219723 **Seq:** 1
Reported: 05/07/2006
Hospitalisation: Admitted to hospital
Onset Date: 29/12/2005
Outcome: Recovered with sequelae 11/01/2006

Gender: F
Weight: 70.00
Age: 47
DOB: 14/08/1958
Causality: Causality possible

Reaction Detail

Medicine Details:

BUSCOPAN (Suspected) **Reason:** Abdominal pain
40.0 Milligram Daily
Batch: **Started:** 28/12/2005 **Stopped:** 29/12/2005

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219744 **Seq:** 1 **Gender:** M
Reported: 06/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nasal congestion Anorgasmia Dry mouth		Patient experienced a dry mouth, "blood in his spit", congestion of the nose and throat each morning, and sexual dysfunction (also described as "he is unable to reach climax when masturbating, as the sensation in his penis feels dulled").	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219752 **Seq:** 1
Reported: 06/07/2006
Hospitalisation: Admitted to hospital
Onset Date: 08/05/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 86Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormon	Caused or prolonged inpatient hospitalisation	Patient experienced SIADH and	NaCl infusion, fluid restriction, stopped Lasix and Zoloft.
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CARVEDILOL HYDROCHLORIDE (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:** 0

COVERSYL (Other drug) **Reason:** Essential benign hypertension
Batch: **Started:** **Stopped:**

DIGOXIN (Suspected) **Reason:** Otr&nos disord of heart rhythm
Batch: **Started:** **Stopped:** 0

ASTRIX 100 (Suspected) **Reason:** Otr&nos disord of heart rhythm
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/07/2006	Serum osmolality	280-300	09/05/2006	268	
06/07/2006	Sodium	135-145	21/05/2006	132	Hyponatraemia - 123.
06/07/2006	Sodium	135-145	09/05/2006	124	Hyponatraemia - 123.
06/07/2006	Sodium	135-145	10/05/2006	125	Hyponatraemia - 123.
06/07/2006	Sodium	135-145	11/05/2006	123	Hyponatraemia - 123.
06/07/2006	Sodium	135-145	12/05/2006	127	Hyponatraemia - 123.
06/07/2006	Sodium	135-145	13/05/2006	128	Hyponatraemia - 123.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 219752 **Seq:** 1
Reported: 06/07/2006
Hospitalisation: Admitted to hospital
Onset Date: 08/05/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 86Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

COUMADIN (Suspected)				**Reason:**	Otr&nos disord of heart rhythm	
Batch:	**Started:**				**Stopped:**	0
LASIX (Suspected)				**Reason:**	Essential benign hypertension	
Tablet	40.0	Milligram	Daily		Oral	
Batch:	**Started:**				**Stopped:**	09/05/2006
ZOLOFT (Suspected)				**Reason:**	Depression	
Tablet	25.0	Milligram	Daily		Oral	
Batch:	**Started:**				**Stopped:**	09/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/07/2006	Sodium	135-145	15/05/2006	130	Hyponatraemia - 123.
06/07/2006	Sodium	135-145	18/05/2006	134	Hyponatraemia - 123.
06/07/2006	Sodium	135-145	01/06/2006	131	Hyponatraemia - 123.
06/07/2006	Urine Sodium		09/05/2006	66	
06/07/2006	Urine osmolality	40-140	09/05/2006	592	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 220265 **Seq:** 1 **Gender:** M
Reported: 21/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22
Onset Date: 04/04/2006 **DOB:** 28/11/1983
Outcome: Recovered 05/04/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Patient presented with syncopal episode - generalised increased tone, no clonic activity	Tramadol SR and Sertraline

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:**
Tablet, modified release 200.0 Milligram Daily Oral
Batch: **Started:** 03/04/2006 **Stopped:** 04/04/2006

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 220300 **Seq:** 1 **Gender:** F
Reported: 24/07/2006 **Weight:** 93.00
Hospitalisation: Required a visit to the doctor **Age:** 37
Onset Date: 01/06/2006 **DOB:** 31/03/1969
Outcome: Recovered 16/06/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Burning sensation		Patient experienced tingling, burning sensation on face (face felt like burning), nerve-like feeling mainly felt on face, no rash but felt like there should have been.	Xydep was ceased.

Medicine Details:

Xydep (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 01/06/2006 **Stopped:** 16/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 220764 **Seq:** 1 **Gender:** M
Reported: 14/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Depression Dizziness Drug ineffective Headache Paraesthesia		Headache, dizziness, tingles in arms and neck, return of suicidal thoughts and depression. Switched to Efexor which he found ineffective	Efexor ceased. Returned to taking Zoloft at a dose of 50mg.

Medicine Details:

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

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 220799 **Seq:** 1
Reported: 15/08/2006
Hospitalisation:
Onset Date: 08/08/2003
Outcome: Not yet recovered

Gender: F
Weight: 55.00
Age: 33
DOB: 25/08/1969
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life	I was given 600mg of pethidine in 19 hours and I was also taking the drug sertraline at the time. I suffered a major seizure and according to doctors had a cardiac arrest which required CPR. I believe mixing the two drugs resulted in serotonin syndrome.	CPR and intubation was commenced, Pethidine injections were stopped and I was transferred to a larger hospital for management. Once transferred I was observed for 24 hours, then
Cardiac arrest	Life		
Drug interaction	Life		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:**

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

PETHIDINE HYDROCHLORIDE (Interaction) **Reason:** Other disturbance of sensation

Injection 600.0 Milligram Daily Intramuscular

Batch: Unknown **Started:** 08/07/2003 **Stopped:** 08/08/2003 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 220848 **Seq:** 1 **Gender:** F
Reported: 17/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention Urinary tract infection		Urinary retention, urinary tract infection.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 220914 **Seq:** 1 **Gender:** F
Reported: 21/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Increased appetite Insomnia		Patient complained she could not sleep and had increased appetite.	GenRx Sertraline ceased.

Medicine Details:

NEXIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANAMAX (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:**

GenRx Sertraline (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** 29/05/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221008 **Seq:** 1 **Gender:** F
Reported: 24/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Anxiety Confusional state Nausea Pyrexia Rash pruritic		Pt complained of pain in her wrist from an allergic drug reaction and also suffered from a itchy rash all over body including palms of hands, pt also was nauseous. Pt also had anxiety, tachycardia fever and confusion which was thought to multifactorial, norpethidine, tramadol, neck pain, UTI, benzodiazepine withdrawal.	Pt was given IV hydrocortisone and phenergan, pt refused analgesia for pain, also pt's panadeine forte and naropin were ceased and pt was given only regular paracetamol

Medicine Details:

ALPHAPRESS (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

TRITACE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PROTHIADEN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

VALIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to penicillins, tetracyclines, procaine, sulpha, flagyl, maloprin, chlorquin, zantac, lasix, buscopan, quinine, imdur, indocid, brufen, tetanus toxiod, morphine, maxolon, stemetil, insect bites/stings and catgut.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221008 **Seq:** 1 **Gender:** F
Reported: 24/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia			

Medicine Details:

PREMARIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FLIXOTIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

VENTOLIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Allergy to penicillins, tetracyclines, procaine, sulpha, flagyl, maloprin, chlorquin, zantac, lasix, buscopan, quinine, imdur, indocid, brufen, tetanus toxiod, morphine, maxolon, stemetil, insect bites/stings and catgut.

Report Detail

Case Number: 221008 **Seq:** 1 **Gender:** F
Reported: 24/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detai

Medicine Details:

PANADEINE FORTE (Suspected)			**Reason:**		
Batch:	**Started:**			**Stopped:**	
TRAMADOL HYDROCHLORIDE (Suspected)			**Reason:**		
Capsule	50.0	Milligram	As necessary	Oral	
Batch:	**Started:**			**Stopped:**	0

Laboratory Investigations:

Additional Information:

Allergy to penicillins, tetracyclines, procaine, sulpha, flagyl, maloprin, chlorquin, zantac, lasix, buscopan, quinine, imdur, indocid, brufen, tetanus toxiod, morphine, maxolon, stemetil, insect bites/stings and catgut.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221173 **Seq:** 1
Reported: 29/08/2006
Hospitalisation:
Onset Date: 04/08/2006
Outcome: Not yet recovered

Gender: M
Weight: 30.00
Age: 11
DOB: 26/12/1994
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyomyositis	Life	Obturator internus pyomyositis, presented febrile and right sided limp for 4 days.	Obturator internus pyomyositis.
Gait disturbance	Life		
Pyrexia	Life		

Medicine Details:

RITALIN (Other drug) **Reason:** Behavior disorders of childhod

Capsule	40.0	Milligram	Daily	Oral

Batch: **Started:** **Stopped:** 0

ZOLOFT (Suspected) **Reason:** Depression

Tablet	50.0	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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221177 **Seq:** 1
Reported: 29/08/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 04/08/2006
Outcome: Not yet recovered

Gender: F
Weight: 68.00
Age: 29
DOB: 13/08/1976
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tearfulness Paranoia Thinking abnormal		Teary, paranoid, scared of childs safety from oneself. When saw violent, dangerous situations on TV, felt that could be then doing it	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 04/08/2006 **Stopped:** 04/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221230 **Seq:** 1 **Gender:** M
Reported: 30/08/2006 **Weight:** 80.00
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 11/06/1967
Outcome: Recovered 11/08/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Life	'Grand mal fit', requiring 24 hours entubation, only one previous fit in 1989. Came on 12 hours after taking first Zoloft 50mg for depression	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram 1 time Oral
Batch: **Started:** 09/08/2006 **Stopped:** 09/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221236 **Seq:** 1
Reported: 31/08/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 15/02/2004
Outcome: Recovered

Gender: M
Weight: 92.00
Age: 71
DOB: 02/05/1932
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration			

Medicine Details:

CELEBREX (Other drug) **Reason:** Osteoarthritis
Capsule 200.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 2004

ZYLOPRIM (Other drug) **Reason:** Gout
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 01/01/2002 **Stopped:** 31/05/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221261 **Seq:** 1 **Gender:** F
Reported: 31/08/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Restless legs syndrome Myalgia		Muscle pain in legs, especially in calves and may have restless leg syndrome.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221311 **Seq:** 1
Reported: 01/09/2006
Hospitalisation:
Onset Date: 26/08/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 16
DOB: 14/04/1990
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Patient took 50mg tablet of Zoloft prescribed the previous day by GP, and again 50mg Zoloft the following day. She experienced headache, nausea, agitation and akathisia plus strong intrusive suicidal thoughts (previously had had vague passive ideas of "not wanting to be here" with no suicidal intent). Strength of suicidal "urges" caused her to have series of panic attacks, and hence contact with Child and Adolescent Mental Health Service by phone on 28 August and consultation on 29 August by which time symptoms were still present but subsiding as had not had any Zoloft since 27 August.	To cease medication, reassurance as to nature of reaction. Mother to closely supervise. Follow-up appointments with GP and CAMHS clinic.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: ? **Started:** 26/08/2006 **Stopped:** 27/08/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221311 **Seq:** 1 **Gender:** F
Reported: 01/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 16
Onset Date: 26/08/2006 **DOB:** 14/04/1990
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Akathisia Nausea Suicidal ideation			

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: ? **Started:** 26/08/2006 **Stopped:** 27/08/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221408 **Seq:** 1 **Gender:** F
Reported: 05/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal.	Taken off Zoloft and Valium and put back on Prothiaden.

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

VALIUM (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221524 **Seq:** 1 **Gender:** M
Reported: 08/09/2006 **Weight:** 100.00
Hospitalisation: **Age:** 49Y
Onset Date: 01/03/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams Flatulence		The patient reports experiencing vivid, intense dreams since commencing treatment with sertraline. These were not present prior to commencing the medication. The dreams are notable for bizarre content. Additionally, the patient reports significant flatus since commencing	Nil treatment required.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 150.0 Milligram Oral
Batch: **Started:** 15/02/2006 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 221553 **Seq:** 1 **Gender:** M
Reported: 12/09/2006 **Weight:** 85.00
Hospitalisation: **Age:** 50
Onset Date: 08/04/2004 **DOB:** 26/12/1953
Outcome: Recovered 08/08/2006 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Apathy Confusional state Lethargy Nausea		Increasing sense of depression to the point where every use of Zoloft increased the depressiveness, nausea, lethargy, demotivation, interlectual confusion, reduction in acuity and an over all sense of being in a drug induced haze.	Zoloft ceased.

Medicine Details:

COVERSYL (Other drug) **Reason:** Essential benign hypertension
Tablet 4.0 Milligram Oral
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

When patient took Zoloft again, he experienced the same symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221583 **Seq:** 1 **Gender:** F
Reported: 13/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 17Y
Onset Date: 15/06/2006 **DOB:**
Outcome: Recovered 30/06/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Confusional state Coordination abnormal Eye pain Medication error Mydriasis Nystagmus Photophobia		Severe rotatory fixation nystagmus associated with ataxis, vertigo, mydriasis, photophobia, nausea and eye lasting a further three weeks. Incorrect doe administrated	Ceased Zoloft

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 07/06/2006 **Stopped:** 13/06/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221583 **Seq:** 1 **Gender:** F
Reported: 13/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 17Y
Onset Date: 15/06/2006 **DOB:**
Outcome: Recovered 30/06/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vertigo			

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 07/06/2006 **Stopped:** 13/06/2006

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221703 **Seq:** 1 **Gender:** F
Reported: 19/09/2006 **Weight:** 61.60
Hospitalisation: **Age:** 81
Onset Date: 12/10/2005 **DOB:** 17/05/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia, nausea, vomiting, diarrhoea, generalised lethargy, anorexia and mild increase in confusion.	Sertraline ceased. Admission for fluid restriction and NaCL supplementation
Anorexia	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MOCLOBEMIDE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
MAXOLON (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
PARACETAMOL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
OMEPRAZOLE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/09/2006	Sodium		08/11/2005	113	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221703 **Seq:** 1 **Gender:** F
Reported: 19/09/2006 **Weight:** 61.60
Hospitalisation: **Age:** 81
Onset Date: 12/10/2005 **DOB:** 17/05/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Lethargy	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

TEMAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 4 weeks

INDAPAMIDE HEMIHYDRATE (Suspected) **Reason:** Essential benign hypertension
Tablet 1.3 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 0

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221703 **Seq:** 1 **Gender:** F
Reported: 19/09/2006 **Weight:** 61.60
Hospitalisation: **Age:** 81
Onset Date: 12/10/2005 **DOB:** 17/05/1924
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PERINDOPRIL (Suspected) **Reason:** Essential benign hypertension
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221705 **Seq:** 1
Reported: 19/09/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 11/08/2006
Outcome: Unknown

Gender: M
Weight: 80.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion Epistaxis		Bruising - 3cm round bruises, on right arm x 2, left shin x 3 and epistaxsis x 2.	

Medicine Details:

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

Tablet 75.0 Milligram Daily Oral

Batch: **Started:** 28/06/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221713 **Seq:** 1 **Gender:** U
Reported: 19/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient experienced weight increased " weight has grown over 20kgs " since taking Zoloft	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

Tablet 150.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221737 **Seq:** 1 **Gender:** F
Reported: 19/09/2006 **Weight:** 65.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective Depression Drug therapy changed		Increase in depression after changing from Zoloft to GenRx Sertraline.	GenRx Sertraline discontinued.

Medicine Details:

GenRx Sertraline (Suspected) **Reason:** Depression

Tablet 200.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221767 **Seq:** 1 **Gender:** F
Reported: 20/09/2006 **Weight:** 103.00
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 11/12/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Polydactyly	Congenital anomaly / birth defect	Baby was born with an extra little toe on left	
Drug exposure during pregnancy	Congenital anomaly / birth defect		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

25mg to 50mg in the first trimester of her pregnancy and reduced to 25mg in the third trimester.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221822 **Seq:** 1 **Gender:** F
Reported: 22/09/2006 **Weight:** 0.00
Hospitalisation: **Age:** 35Y
Onset Date: 17/08/2006 **DOB:**
Outcome: Recovered 20/08/2006 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Premature labour Uterine pain		After taking 50mg dose of Zoloft patient developed lower abdominal pain that felt like contractions or more like "afterbirth pains" and uterine pain	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 17/08/2006 **Stopped:** 20/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced same reactions after each dose of Zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221897 **Seq:** 1 **Gender:** M
Reported: 26/09/2006 **Weight:** 100.00
Hospitalisation: Admitted to hospital **Age:** 21
Onset Date: 25/07/2006 **DOB:** 04/10/1984
Outcome: Recovered 26/07/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Muscle spasticity	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMAL SR (Suspected) **Reason:** Pain
Tablet 200.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:** 25/07/2006

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 25/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Further episode of tachycardia, sweating, increase tone and reflex at 1500. Initial presentation - 1100.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 221897 **Seq:** 1 **Gender:** M
Reported: 26/09/2006 **Weight:** 100.00
Hospitalisation: Admitted to hospital **Age:** 21
Onset Date: 25/07/2006 **DOB:** 04/10/1984
Outcome: Recovered 26/07/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TRAMAL SR (Suspected) **Reason:** Pain

Tablet 200.0 Milligram As necessary Oral

Batch: **Started:** **Stopped:** 25/07/2006

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Dose Unspecified Daily Oral

Batch: **Started:** **Stopped:** 25/07/2006

Laboratory Investigations:

Additional Information:

Further episode of tachycardia, sweating, increase tone and reflex at 1500. Initial presentation - 1100.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222433 **Seq:** 1 **Gender:** F
Reported: 13/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood sodium decreased	Caused or prolonged inpatient hospitalisation		required IV fluids

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Elderly female patient, age over 60 years.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222457 **Seq:** 1 **Gender:** F
Reported: 16/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		A "feeling of wanting to jump off a cliff with her babies".	Zoloft discontinued.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222459 **Seq:** 1 **Gender:** F
Reported: 16/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Cough.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Obsessive compulsive neurosis
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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222537 **Seq:** 1 **Gender:** F
Reported: 18/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood sodium decreased	Caused or prolonged inpatient hospitalisation	Low sodium levels	IV Fluids, Zoloft isn not

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222602 **Seq:** 1 **Gender:** F
Reported: 19/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Crying Hallucination, auditory Nausea		Had "dreadful noises in her head" and they've driven her to think about suicide - a type of tinnitus. It "feels like the CNS is working overtime". The noise in her head "sounds like cicadas or as if you've got your head near a high pressure air hose when it's being released". The noise is so bad that sometimes "she just sits and howls and she feels like she's suicide material. Also reports being "sick in the tummy", sometimes is really shaky and	Zoloft discontinued. Serepax gives her some relief and calms it

Medicine Details:

AVAPRO (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient reports that she took half a tablet of Zoloft a day for four days, then increased it to one tab daily and experienced symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222602 **Seq:** 1 **Gender:** F
Reported: 19/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Screaming Suicidal ideation Tinnitus Tremor			Zoloft discontinued. Serepax gives her some relief and calms

Medicine Details:

AVAPRO (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 1.0 Dose Unspecified Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Additional Information:

Patient reports that she took half a tablet of Zoloft a day for four days, then increased it to one tab daily and experienced symptoms.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222720 **Seq:** 1 **Gender:** F
Reported: 27/10/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Contusion Paraproteinaemia		Surgery on her knee, seven to eight bruising spots, paraprotein levels of 3	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222846 **Seq:** 1
Reported: 01/11/2006
Hospitalisation: Admitted to hospital
Onset Date: 02/10/2006
Outcome: Recovered

Gender: F
Weight: 68.00
Age: 87Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Life	Blurred vision, headache, slowed speech and vomiting. Suffered 2 x tonic clonic seizures (approx 1 min) in ED. Seizures due to hyponatraemia and hyponatraemia attributed to SIADH.	Recieved hypertonic saline 3% (130mL over 2 hrs.
Convulsion	Life		
Dysarthria	Life		
Headache	Life		
Hyponatraemia	Life		
Inappropriate antidiuretic hormon	Life		
Vomiting	Life		

Medicine Details:

ATORVASTATIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

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

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

ATENOLOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/11/2006	Creatinine		01/10/2006	60mL/min	
01/11/2006	Potassium		02/10/2006	3.5	
01/11/2006	Serum osmolality		01/10/2006	256	
01/11/2006	Sodium		01/10/2006	117	
01/11/2006	Urine Potassium		01/10/2006	29	
01/11/2006	Urine Sodium		01/10/2006	94	
01/11/2006	Urine osmolality		01/10/2006	348	

Additional Information:

Patient had previously (~18 months) had an admission due to seizures believed to be caused by low sodium. It was concluded at the time this was due to polydipsia. (was not on any drugs implicated with decreased sodium).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222846 **Seq:** 1
Reported: 01/11/2006
Hospitalisation: Admitted to hospital
Onset Date: 02/10/2006
Outcome: Recovered

Gender: F
Weight: 68.00
Age: 87Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

CLOPIDOGREL (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
ISOSORBIDE MONONITRATE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
AMLODIPINE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
COLOXYL WITH SENNA (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Patient had previously (~18 months) had an admission due to seizures believed to be caused by low sodium. It was concluded at the time this was due to polydipsia. (was not on any drugs implicated with decreased sodium).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222846 **Seq:** 1
Reported: 01/11/2006
Hospitalisation: Admitted to hospital
Onset Date: 02/10/2006
Outcome: Recovered

Gender: F
Weight: 68.00
Age: 87Y
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

OMEPRAZOLE (Other drug)		**Reason:**	
Batch:	**Started:**		**Stopped:**
SERTRALINE HYDROCHLORIDE (Suspected)		**Reason:**	Depression
	50.0 Milligram		Daily
Batch:	**Started:** 02/09/2006		**Stopped:** 02/10/2006

Laboratory Investigations:

Additional Information:

Patient had previously (~18 months) had an admission due to seizures believed to be caused by low sodium. It was concluded at the time this was due to polydipsia. (was not on any drugs implicated with decreased sodium).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222982 **Seq:** 1 **Gender:** M
Reported: 08/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 10/10/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia		Patient complained he could not sleep.	

Medicine Details:

NEXIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANAMAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

GenRx Sertraline (Suspected) **Reason:**
Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 222983 **Seq:** 1 **Gender:** F
Reported: 08/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 10/10/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia Increased appetite		Patient complained she could not sleep and had an increased appetite.	

Medicine Details:

NEXIUM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANAMAX (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

GenRx Sertraline (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Detail

Case Number: 223061 **Seq:** 1 **Gender:** F
Reported: 13/11/2006 **Weight:**
Hospitalisation: **Age:** 99U
Onset Date: 16/08/2006 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizures x 3 up to 5 minutes, maternal sertraline exposure.	
Convulsion neonatal	Caused or prolonged inpatient hospitalisation		
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223111 **Seq:** 1
Reported: 14/11/2006
Hospitalisation: Admitted to hospital
Onset Date: 22/08/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 16
DOB: 30/07/1990
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life	Since patient commenced Zoloft - insomnia, suicidal intentions, mood became angrier. First suicide attempt - overdosed on 12 tablets of sertraline	Taper and cease medication over a period of a few days.
Anger	Life		
Insomnia	Life		
Intentional overdose	Life		
Suicidal ideation	Life		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 01/08/2006 **Stopped:** 08/08/2006 0

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 08/08/2006 **Stopped:** 15/08/2006 0

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 15/08/2006 **Stopped:** 22/08/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223122 **Seq:** 1
Reported: 14/11/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 22/09/2006
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 60Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Agitation Anxiety Restlessness		For a week, experienced tremor, agitation, anxiety and restlessness.	

Medicine Details:

PARIET (Other drug) **Reason:** Other diseases of esophagus

Tablet 20.0 Milligram Daily Oral

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

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223141 **Seq:** 1 **Gender:** F
Reported: 14/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: 04/11/2006 **DOB:** 27/05/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting		Nausea and vomiting soon after starting Zoloft treatment	Ceased treatment with Zoloft

Medicine Details:

PANADEINE (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified 4 times Oral
Batch: **Started:** **Stopped:** 0

XANAX (Other drug) **Reason:**
Tablet 1.0 Milligram 4 times Oral
Batch: **Started:** **Stopped:** 0

ZOLOFT (Suspected) **Reason:**
Tablet 100.0 Milligram 1 time Oral
Batch: **Started:** 01/11/2006 **Stopped:** 10/11/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223162 **Seq:** 1 **Gender:** F
Reported: 15/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 62Y
Onset Date: 29/09/2006 **DOB:**
Outcome: Recovered 01/10/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation	On the third dose of Zoloft, took one dose in the morning and went back to sleep. Woke up sweating with vomiting and nausea. One hour later was vomiting so hard her husband called the ambulance.	Went to hospital in semi conscious state. Was observed for several hours but not admitted.
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Nausea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZE (Other drug) **Reason:**
10.0 Milligram
Batch: **Started:** 15/11/2005 **Stopped:**

CORTISONE ACETATE (Other drug) **Reason:**
Tablet 12.5 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

SLOW-K (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram 1 time Oral
Batch: **Started:** 29/09/2006 **Stopped:** 29/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Natures own chromium picolinate, Blavkmore's Bio-Iron, Blackmore's B12, Blackmore's Magnesium Aspatate, Caltrate.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223163 **Seq:** 1 **Gender:** F
Reported: 15/11/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 34Y
Onset Date: 05/09/2006 **DOB:**
Outcome: Recovered 09/09/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug therapy changed Dyspepsia Nausea		Patient changed from Zoloft to Chem Mart sertraline. Zoloft was well tolerated, but generic band caused heartburn and nausea. For the first 2/7 and on the third day patient vomited several times.	Drug ceased. Went back on Zoloft and recovered.

Medicine Details:

Symbicort Turbuhaler (Other drug) **Reason:**
Inhalation 2.0 Dose Unspecified Inhalation
Batch: **Started:** **Stopped:**

Alvesco (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SINGULAIR (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PANADEINE FORTE (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
Tablet 1.0 Dose Unspecified As necessary Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Blackmore's Evening Primrose Oil, Fish Oil, glucosamine, Vit E, Nature's Sunsjine licorice roast.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223163 **Seq:** 1 **Gender:** F
Reported: 15/11/2006 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 34Y
Onset Date: 05/09/2006 **DOB:**
Outcome: Recovered 09/09/2006 **Causality:** Causality possible

Reaction Detail

Medicine Details:

PARACETAMOL (Other drug)			**Reason:**	Otr&unsp vertebrogen pain synd	
	8.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
Chem Mart Sertraline (Suspected)			**Reason:**		
Tablet	200.0	Milligram	Daily	Oral	
Batch:	**Started:**	05/09/2006		**Stopped:**	0

Laboratory Investigations:

Additional Information:

Blackmore's Evening Primrose Oil, Fish Oil, glucosamine, Vit E, Nature's Sunsjine licorice roast.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223285 **Seq:** 1 **Gender:** F
Reported: 17/11/2006 **Weight:** 161.50
Hospitalisation: **Age:** 51Y
Onset Date: 29/09/2006 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Agitation Constipation Dizziness Nausea		Tremor, dizziness, insomnia, agitation,	Withdrawal of sertraline.

Medicine Details:

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

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 26/09/2006 **Stopped:** 06/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223339 **Seq:** 1 **Gender:** F
Reported: 17/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Akathisia Coeliac disease Drug withdrawal syndrome Lactose intolerance Motion sickness		akathisia, body is ruined, cannot eat gluten, cannot eat lactose, cannot eat table sugar, cannot eat fructose, stomach symptoms, neurological symptoms, withdrawal symptoms, constantly motion sick, cannot wake up before body is ready, cannot stay up past 8.30, plunged into twilight zone	

Medicine Details:

ZOLOFT (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223365 **Seq:** 1 **Gender:** F
Reported: 21/11/2006 **Weight:** 65.00
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 28/12/1958
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations Arrhythmia Drug interaction		Consumer started taking Fexotabs 120mg at night with half Xydep 100mg at night for her allergies. About 4 hours after taking Fexotabs she experienced racing heart and arrythmias. This occured on a couple of nights.	

Medicine Details:

Xydep (Interaction) **Reason:** Otr ecz&der due otr&unsp cause
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/10/2002 **Stopped:** 0

Fexotabs (Interaction) **Reason:** Otr ecz&der due otr&unsp cause
Tablet 120.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Consumer dose not experience these side effects if she takes the tablets 12 hours apart.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223393 **Seq:** 1 **Gender:** F
Reported: 22/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 20Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Patient fell asleep after taking medication.	Drug discontinued.

Medicine Details:

GenRx Sertraline (Suspected) **Reason:**

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223394 **Seq:** 1 **Gender:** F
Reported: 22/11/2006 **Weight:** 0.00
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Patient fell asleep after taking medication.	Drug discontinued. Changed back to Zoloft.

Medicine Details:

GenRx Sertraline (Suspected) **Reason:**

Tablet 200.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223438 **Seq:** 1
Reported: 22/11/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 55Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	seizure	

Medicine Details:

ZOLOFT (Suspected) **Reason:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Family history of epilepsy

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223455 **Seq:** 1 **Gender:** U
Reported: 23/11/2006 **Weight:** 65.00
Hospitalisation: Required a visit to the doctor **Age:** 16
Onset Date: 02/09/2006 **DOB:** 21/01/1990
Outcome: Recovered 05/09/2006 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mydriasis		Dilated pupils - extreme.	

Medicine Details:

DEXAMPHETAMINE SULPHATE (Other drug) **Reason:** Behavior disorders of childhod
22.5 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 29/08/2006 **Stopped:** 04/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Similar reaction with Luvon and Den.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223557 **Seq:** 1 **Gender:** F
Reported: 28/11/2006 **Weight:** 70.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 35
Onset Date: 07/10/2006 **DOB:** 10/10/1970
Outcome: Recovered 12/10/2006 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Caused or prolonged inpatient hospitalisation	Abdominal/epigastric pain which occured one week after starting generic tablets.	Return to usual brand led to pain ceasing immediately.
Abdominal pain upper	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLEXANE (Other drug) **Reason:**
Injection Subcutaneous
Batch: **Started:** **Stopped:**

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

GenRx Sertraline (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 30/09/2006 **Stopped:** 10/10/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223869 **Seq:** 1 **Gender:** M
Reported: 06/12/2006 **Weight:** 75.00
Hospitalisation: **Age:** 38Y
Onset Date: 01/01/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nocturia	Incapacity/disability	Nocturia 1-2 times nightly	
Urinary incontinence	Incapacity/disability	1 episode of urinary incontinence whilst awake	
Micturition urgency	Incapacity/disability	urinary urgency and frequency, without polyuria or polydipsia	reduction of dose to 50mg, and addition of bupropion 150mg mane due to inadequate antidepressant effect from sertraline 50mg monotherapy
Enuresis	Incapacity/disability	with 1 episode of enuresis	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet Oral
Batch: **Started:** 01/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/12/2006	Haematology				BSL, EUC, Ca, PO4, MSU PSA all normal

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 223937 **Seq:** 1 **Gender:** M
Reported: 08/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 36Y
Onset Date: 22/08/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tympanic membrane hyperaemia		Inflamed tympanic membrane	
Deafness		deafness permanent, tinnitus	
Labyrinthitis			
Nystagmus			
Tinnitus			
Vertigo			

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 0

DIAZEPAM (Suspected) **Reason:**
5.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224052 **Seq:** 1 **Gender:** M
Reported: 13/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		experienced " brain shakes and "electric shock through the head" after being " forcibly removed off sertraline"	
Mania		experienced "brain shakes" and "electric shock through the head" after being "forcibly removed off sertraline"	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient reports he overdosed on caffeine 1.3g , taurine and nicotine 200mg and was admitted to hospital after 36 hours of no sleep and mania symptoms, was taken off Zoloft after being diagnosed with bipolar disorder at hospital and being treated with a cocktail of drugs for bipolar disorder

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224255 **Seq:** 1 **Gender:** F
Reported: 20/12/2006 **Weight:** 0.00
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fall		After drinking 2-3 glasses of alcohol, she seems more affected by the alcohol and has falls which she doesn't remember	
Alcohol intolerance		The patient reports after drinking 2-3 glasses pf alcohol she seems to be more affected by the alcohol and has falls which she doesn't remember. Her family report that when she drank alcohol she "acted drunker"	
Amnesia			
Mood swings			

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

ALCOHOL (Suspected) **Reason:**
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking unspecified blood pressure tablets.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224385 **Seq:** 1
Reported: 04/01/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 24/11/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Agitation Diarrhoea Pyrexia Serotonin syndrome Tremor		Sweating, fever, agitation, diarrhoea,	Stopped Tramal.

Medicine Details:

TRAMAL (Interaction) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 24/11/2006 **Stopped:** 25/11/2006

ZOLOFT (Interaction) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 15/03/2006 **Stopped:** 0

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

AZOPT EYE DROPS (Other drug) **Reason:**
2.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224385 **Seq:** 1
Reported: 04/01/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 24/11/2006
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Detail

Medicine Details:

Lumigan (Other drug) **Reason:**

1.0 Dose Unspecified

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

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224630 **Seq:** 1
Reported: 12/01/2007
Hospitalisation:
Onset Date: 09/09/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 48
DOB: 08/01/1958
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Eczema	Caused or prolonged inpatient hospitalisation	Patient was hospitalised for eczematous eruption of the trunk, face and scalp preceded by pruritus	Sertraline, Zyrtec, Panet, Urea in WSP, Menthol and camphor, Advantan, Dermeze, Hamilton bath oil, normal saline compresses, Elecon, Panadol Temezepam. Wet dressings.
Pruritus	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADOL (Other drug) **Reason:**
Batch: **Started:** 19/05/2006 **Stopped:**

PARIET (Other drug) **Reason:**
Batch: **Started:** L TERM **Stopped:**

TEMAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Batch: **Started:** 01/06/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/01/2007	Other data				

Additional Information:

Past History: Transient ischemic attack, gstric ulcer, gout, drug abuse, alcohol abuse

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224630 **Seq:** 1
Reported: 12/01/2007
Hospitalisation:
Onset Date: 09/09/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 48
DOB: 08/01/1958
Causality: Causality possible

Reaction Detail

Medicine Details:

Peg Interferon Alfa-2B (Suspected)			**Reason:**	Unspecified cirrhosis of liver	
	150.0	Microgram	Daily		
Batch:	**Started:**	19/05/2006		**Stopped:**	03/11/2006 0
RIBAVIRIN (Suspected)			**Reason:**		
Capsule	1200.0	Milligram	Daily		Oral
Batch:	**Started:**	19/05/2006		**Stopped:**	09/11/2006

Laboratory Investigations:

Additional Information:

Past History: Transient ischemic attack, gstric ulcer, gout, drug abuse, alcohol abuse

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224729 **Seq:** 1 **Gender:** F
Reported: 16/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 57Y
Onset Date: 09/01/2007 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haemoptysis Irritability Lower respiratory tract infection Sinusitis Tremor		haemoptysis, chest infection, irritable, tremor, sinus infection	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224871 **Seq:** 1 **Gender:** F
Reported: 19/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 50Y
Onset Date: 15/09/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal impairment Blood creatinine increased Disorientation		renal disorder, creatinine increased,	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
100.0 Milligram
Batch: **Started:** 15/09/2005 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 224912 **Seq:** 1 **Gender:** F
Reported: 22/01/2007 **Weight:** 75.00
Hospitalisation: Required a visit to the doctor **Age:** 36
Onset Date: **DOB:** 21/05/1970
Outcome: Recovered 10/06/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Menorrhagia		Developed menorrhagia following 18 months treatment with sertraline.	Ceased drug.

Medicine Details:

RISPERIDONE (Other drug) **Reason:** Other psychoses
1.5 Milligram Daily
Batch: **Started:** 29/12/2004 **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 23/02/2006 **Stopped:** 27/09/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Menorrhagia persisted >3 months.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225021 **Seq:** 1 **Gender:** F
Reported: 24/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise Nausea		Patient felt sick on taking medication.	

Medicine Details:

Terry White Chemists Sertraline (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had taken Zoloft in past with no effect.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225036 **Seq:** 1 **Gender:** F
Reported: 24/01/2007 **Weight:** 67.00
Hospitalisation: Required a visit to the doctor **Age:** 45
Onset Date: 21/12/2006 **DOB:** 09/09/1961
Outcome: Recovered 26/12/2006 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oesophageal pain	Incapacity/disability	Patient took 1/2 Sertraline-DP 100mg tablet, within 10-20 minutes following ingestion patient reported severe burning, hyperacidity, extreme difficulty swallowing and subsequently vomited. The next day, patient re-challenged with 1/2 tablet and experienced the same reaction. 3rd and 4th rechallenge yielded same result. Patient ceased using that brand of medication and now taking zoloft 100mg (1/2 d) with no ill effects	Patient reported using antacid with some relief
Dysphagia	Incapacity/disability		
Hyperchlorhydria	Incapacity/disability		

Medicine Details:

Sertraline-DP 100 (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 21/12/2006 **Stopped:** 26/12/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cert:rechall

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225036 **Seq:** 1 **Gender:** F
Reported: 24/01/2007 **Weight:** 67.00
Hospitalisation: Required a visit to the doctor **Age:** 45
Onset Date: 21/12/2006 **DOB:** 09/09/1961
Outcome: Recovered 26/12/2006 **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Incapacity/disability		

Medicine Details:

Sertraline-DP 100 (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 21/12/2006 **Stopped:** 26/12/2006 0

Laboratory Investigations:

Additional Information:

Cert:rechall

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225190 **Seq:** 1 **Gender:** F
Reported: 30/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 63
Onset Date: 15/01/2007 **DOB:** 30/10/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oligodipsia	Incapacity/disability	hypodipsia, shakiness, diarrhoea, yawning, nausea, insomnia, appetite loss, indigestion, palpitations	
Tremor	Incapacity/disability	persisting	
Yawning	Incapacity/disability	which ceased	
Diarrhoea	Incapacity/disability	which has settled	
Palpitations	Incapacity/disability	which has settled	
Anorexia	Incapacity/disability		

Medicine Details:

NEULACTIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

COVERSYL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 22/12/2006 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225190 **Seq:** 1 **Gender:** F
Reported: 30/01/2007 **Weight:** 0.00
Hospitalisation: **Age:** 63
Onset Date: 15/01/2007 **DOB:** 30/10/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia	Incapacity/disability		
Insomnia	Incapacity/disability		
Nausea	Incapacity/disability		

Medicine Details:

NEULACTIL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

COVERSYL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 22/12/2006 **Stopped:** 0

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225341 **Seq:** 1
Reported: 02/02/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 19/12/2006
Outcome: Not yet recovered

Gender: F
Weight: 102.00
Age: 35
DOB: 02/05/1971
Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Burning sensation Abdominal pain upper Hyperhidrosis		Burning sensation, arms & face and sweating, epigastric abdominal pain.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 18/12/2006 **Stopped:** 21/12/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced same symptoms the next day.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225431 **Seq:** 1 **Gender:** F
Reported: 06/02/2007 **Weight:** 58.00
Hospitalisation: **Age:** 49
Onset Date: 24/02/2007 **DOB:** 16/07/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia	Incapacity/disability		
Dizziness	Incapacity/disability		
Drug withdrawal syndrome	Incapacity/disability		
Dyspnoea	Incapacity/disability		
Lethargy	Incapacity/disability		
Mental impairment	Incapacity/disability		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 24/12/2002 L TERM **Stopped:** 23/01/2007 discontinued

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225431 **Seq:** 1 **Gender:** F
Reported: 06/02/2007 **Weight:** 58.00
Hospitalisation: **Age:** 49
Onset Date: 24/02/2007 **DOB:** 16/07/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensation of heaviness	Incapacity/disability		
Vertigo	Incapacity/disability		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 24/12/2002 L TERM **Stopped:** 23/01/2007 discontinued

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225509 **Seq:** 1
Reported: 07/02/2007
Hospitalisation: Required a specialist consultation
Onset Date: 01/10/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 18Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance Night blindness Visual field defect		While being outside during the day he can only see a lot of white. He can see normally in medium light	

Medicine Details:

Eleva 50 (Suspected) **Reason:** Anxiety neurosis

Tablet 50.0 Milligram 1 time Oral

Batch: **Started:** 01/07/2006 **Stopped:** 23/02/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Eye specialist will test him for degenerative retinal pigmentosis. He is a vegetarian.

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:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225779 **Seq:** 1 **Gender:** F
Reported: 13/02/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Headache		Anxiety and headache.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 225813 **Seq:** 1
Reported: 14/02/2007
Hospitalisation: Required a specialist consultation
Onset Date: 30/01/2007
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 50Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fall Hypersomnia Muscular weakness Tremor		Falling down and sleeping for 20 hours a day; fine tremor in both arms, more pronounced in the left; a few days later this was a whole body tremor, with weakness of arms.	

Medicine Details:

NEURONTIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ENDEP (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

Lyrica (Suspected) **Reason:**
300.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 226127 **Seq:** 1 **Gender:** F
Reported: 26/02/2007 **Weight:** 61.50
Hospitalisation: **Age:** 26
Onset Date: 05/02/2007 **DOB:** 15/03/1980
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash Insomnia		Rash and Insomnia.	Ceased medication and treated with hydrocortisone cream.

Medicine Details:

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

Tablet 100.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 226142 **Seq:** 1
Reported: 22/02/2007
Hospitalisation: Required a visit to the doctor
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 48.00
Age: 33
DOB: 31/10/1973
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Therapy regimen changed		Bilateral galactorrhoea.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/02/2007	Prolactin				Prolactin level normal

Additional Information:

Started approx 2-3 weeks after increasing dose to 100mg.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 226147 **Seq:** 1 **Gender:** F
Reported: 26/02/2007 **Weight:** 0.00
Hospitalisation: **Age:** 57
Onset Date: 03/09/2006 **DOB:** 18/03/1949
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tinnitus	Life	Noise in head is like gas escaping from a pipe, under high pressure and is extremely loud. Each day is a struggle to survive.	
Suicidal ideation	Life		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Alcohol can control this noise it is certainly not tinnitus.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 226357 **Seq:** 1 **Gender:** F
Reported: 06/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 74
Onset Date: 19/02/2007 **DOB:** 09/09/1932
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	hyponatraemia, nausea and vomiting.	Fluid restriction
Nausea	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Niacin (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

CO-ENZYME Q10 (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

MULTIVITAMINS (Suspected) **Reason:**
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/03/2007	Chloride		16/02/2007	86 mmol/L	
06/03/2007	Chloride		19/02/2007	102 mmol/L	
06/03/2007	Sodium		16/02/2007	122 mmol/L	
06/03/2007	Sodium		19/02/2007	138 mmol/L	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 226579 **Seq:** 1
Reported: 13/03/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 15/10/2006
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 49
DOB: 29/08/1957
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain in jaw Anorgasmia Bruxism		Left jaw pain, bruxism and anorgasmia.	Will change SSRI to Lexapro.

Medicine Details:

NEXIUM (Other drug) **Reason:** Other diseases of esophagus

Tablet 20.0 Milligram Daily Oral

Batch: **Started:** 15/09/2004 **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 15/03/2006 **Stopped:** 15/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 226689 **Seq:** 1
Reported: 15/03/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 15/12/2006
Outcome: Recovered

Gender: M
Weight: 78.00
Age: 35
DOB: 01/07/1971
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Poor quality sleep		Patient developed poor sleep, feeling drugged after changing to a generic drug.	Ceased generic drug.

Medicine Details:

LIPITOR (Other drug) **Reason:**

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

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

50.0 Milligram Daily

Batch: **Started:** 15/10/2006 **Stopped:** 01/01/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 226924 **Seq:** 1 **Gender:** F
Reported: 23/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 80
Onset Date: **DOB:** 16/03/1927
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diverticulitis	Caused or prolonged inpatient hospitalisation	Patient has suffered from diverticulitis for 10 years and experienced a flare up witin 1 week of starting Zoloft	
Abdominal pain upper	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

BUSCOPAN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been taking citalopram for 7 years prior to Zoloft. Not yet recovered but almost resolved.

Report Detail

Case Number: 226924 **Seq:** 1
Reported: 23/03/2007
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 80
DOB: 16/03/1927
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PANADOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

BUSCOPAN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:
Patient had been taking citalopram for 7 years prior to Zoloft. Not yet recovered but almost resolved.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 226980 **Seq:** 1
Reported: 26/03/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 04/01/2007
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 39
DOB: 13/12/1967
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Diarrhoea.	Stopped Zoloft.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Batch: **Started:** 30/11/2006 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227250 **Seq:** 1 **Gender:** M
Reported: 03/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 65
Onset Date: **DOB:** 22/06/1941
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Caused or prolonged inpatient hospitalisation	Sweating, palpitations, chest pain,delirium, auditory hallucinations, suicidal ideation, depression worsened.	
Chest pain	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 24/02/2007 S TERM **Stopped:** 02/03/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Physical symptoms resolved on stopping Zoloft but depression/psychosis has not.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227250 **Seq:** 1 **Gender:** M
Reported: 03/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 65
Onset Date: **DOB:** 22/06/1941
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression	Caused or prolonged inpatient hospitalisation		
Hallucination, auditory	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 24/02/2007 S TERM **Stopped:** 02/03/2007 0

Laboratory Investigations:

Additional Information:
Physical symptoms resolved on stopping Zoloft but depression/psychosis has not.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227250 **Seq:** 1 **Gender:** M
Reported: 03/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 65
Onset Date: **DOB:** 22/06/1941
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 24/02/2007 S TERM **Stopped:** 02/03/2007 0

Laboratory Investigations:

Additional Information:

Physical symptoms resolved on stopping Zoloft but depression/psychosis has not.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227510 **Seq:** 1 **Gender:** M
Reported: 12/04/2007 **Weight:** 74.00
Hospitalisation: **Age:** 76
Onset Date: 07/08/2006 **DOB:** 25/05/1930
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema	Caused or prolonged inpatient hospitalisation	Patient had a severe allergic reaction to drugs causing him to fall asleep on his feet and 31 falls in hospital breaking his back. His lips, face and legs swelled up with both his legs are still bad.	
Fall	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Paralysis agitans
Batch: **Started:** 06/06/2006 **Stopped:**

TEGRETOL (Suspected) **Reason:** Otr periph nerve dis not auton
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergies to pneumonia vaccine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227857 **Seq:** 1 **Gender:** M
Reported: 23/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 64Y
Onset Date: 30/01/2007 **DOB:**
Outcome: Recovered 07/02/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Angioedema	Life	Patient experienced angio-oedema, supraglottic soft tissue oedema, stridor, swelling lips and tongue, respiratory distress. Patchy erythematous rash on face and upper trunk.	ICU admission, intubated, IV steroids, adrenaline. Antibiotics to cover the possibility of infective pharyngitis
Rash erythematous	Life		

Medicine Details:

COUMADIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

MAGMIN (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

PULMICORT (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

FLUCLOROLONE ACETONIDE (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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227857 **Seq:** 1 **Gender:** M
Reported: 23/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 64Y
Onset Date: 30/01/2007 **DOB:**
Outcome: Recovered 07/02/2007 **Causality:** Causality possible

Reaction Detail

Medicine Details:

SLOW-K (Other drug)			**Reason:**		
Batch:	**Started:**			**Stopped:**	
IRBESARTAN (Suspected)			**Reason:**	Essential benign hypertension	
Tablet	300.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	31/01/2007
SERTRALINE HYDROCHLORIDE (Suspected)			**Reason:**	Depression	
Tablet	150.0	Milligram	Daily		Oral
Batch:	**Started:**	15/01/2007		**Stopped:**	31/01/2007

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227879 **Seq:** 1 **Gender:** M
Reported: 24/04/2007 **Weight:** 77.00
Hospitalisation: **Age:** 34
Onset Date: 20/02/2007 **DOB:** 25/08/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Incapacity/disability		
Sexual dysfunction	Incapacity/disability		
Suicidal ideation	Incapacity/disability		

Medicine Details:

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

Tablet 75.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 20/04/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227937 **Seq:** 1 **Gender:** F
Reported: 16/04/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: 10/03/2007 **DOB:**
Outcome: Recovered 22/03/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mydriasis Change in sustained attention Dizziness Hyperhidrosis Tremor		Pupil dilatation (wide), sweating, low concentration, dizziness, tremor.	Ceased sertraline.

Medicine Details:

LEVLEN ED (Other drug) **Reason:** Contraception
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** 16/06/2006 **Stopped:**

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 10/03/2007 **Stopped:** 21/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sertraline for 2 days then ceased for a few days, restarted again with 25mg for 4 days then ADR recurr, then ceased again.i

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 227945 **Seq:** 1 **Gender:** M
Reported: 20/04/2007 **Weight:** 81.00
Hospitalisation: Required a visit to the doctor **Age:** 47
Onset Date: 29/01/2007 **DOB:** 21/07/1959
Outcome: Recovered 12/03/2007 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sensitivity of teeth		Hot and cold sensitivity to the teeth fillings causing aching at night.	

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 28/08/2006 **Stopped:** 05/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/04/2007	Other data				nothing abnormal noted on dental review with Xrays

Additional Information:

sensitivity onset 3 months after starting zoloft.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 228499 **Seq:** 1
Reported: 14/05/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 19/03/2007
Outcome: Recovered

Gender: F
Weight: 104.00
Age: 53
DOB: 05/09/1953
Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed Drug eruption Hepatitis Rash erythematous		Severe fixed drug eruption, erythematous wide spread rash and hepatitis.	

Medicine Details:

KARVEZIDE 300/12.5 (Other drug) **Reason:**
Batch: **Started:** 21/07/2005 **Stopped:**

Glucosamine Nos (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** 15/02/2007 **Stopped:** 19/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/05/2007	ALT = SGPT				
14/05/2007	AST = SGOT				
14/05/2007	GGT = SGGT =				
14/05/2007	SAP = ALP				

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 228513 **Seq:** 1 **Gender:** F
Reported: 15/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 39
Onset Date: 18/03/2007 **DOB:** 02/10/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed		Zoloft increased 50 mg daily to 100mg daily 5 days after commencement	
Panic attack		anxious about her health	
Anger			
Anxiety			
Diarrhoea			
Fear			
Self-injurious ideation			

Medicine Details:

VALIUM (Other drug) **Reason:**
5.0 Milligram
Batch: **Started:** **Stopped:**

ZOLOFT (Suspected) **Reason:** Anxiety neurosis
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 14/03/2007 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a long history of anxiety and had previously tolerated Zoloft 200mg. Her Dr believes the events were more likely due to her underlying anxiety

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 228692 **Seq:** 1 **Gender:** M
Reported: 21/05/2007 **Weight:** 78.00
Hospitalisation: **Age:** 46
Onset Date: 16/05/2007 **DOB:** 03/09/1960
Outcome: Not yet recovered 21/05/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Vertigo positional		dizziness similar to vertigo especially when turning head or bending down. Patient had halved dose (to 25mg) for 7 days prior to ceasing medicine	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:** Depression
Tablet 50.0 Milligram Daily Oral
Batch: ? **Started:** 10/02/2007 **Stopped:** 15/05/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

was taking sertraline at 50mg per day for three months.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 228717 **Seq:** 1
Reported: 21/05/2007
Hospitalisation: Admitted to hospital
Onset Date: 10/05/2007
Outcome: Recovered

Gender: F
Weight: 65.00
Age: 45Y
DOB:
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced an epileptic seizure after taking Dozile with Zoloft.	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:** 0

DOZILE (Suspected) **Reason:**
Capsule 25.0 Milligram 1 time
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient last experienced epilepsy 15 years ago and had stopped taking medication 6 years ago.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 228998 **Seq:** 1
Reported: 29/05/2007
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 3.00
Age: 0
DOB: 30/04/2007
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cleft palate		Baby born with cleft lip and palate.	Surgical intervention.

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

100.0 Milligram

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

mother was taking Zoloft throughout pregnancy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 229188 **Seq:** 1 **Gender:** M
Reported: 31/05/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Chest pain Dyspnoea Pancreatitis			

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230008 **Seq:** 1 **Gender:** F
Reported: 20/06/2007 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: 05/06/2007 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombosis		A patient receving Zoloft noticed a small vaginal blood clot	

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 25.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230202 **Seq:** 1 **Gender:** F
Reported: 21/06/2007 **Weight:** 89.00
Hospitalisation: **Age:** 20
Onset Date: 15/05/2007 **DOB:** 07/01/1987
Outcome: Recovered 31/05/2007 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dry skin Exfoliative rash		Dry, sore skin around eyes, peeling, flaking and redness.	

Medicine Details:

IMPLANON IMPLANT (Other drug) **Reason:**

Batch: **Started:** L TERM **Stopped:**

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

Tablet Milligram Daily Oral

Batch: **Started:** 14/05/2007 **Stopped:** 21/05/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230204 **Seq:** 1 **Gender:** M
Reported: 25/06/2007 **Weight:** 80.00
Hospitalisation: Required a visit to the doctor **Age:** 73
Onset Date: 01/05/2006 **DOB:** 20/08/1932
Outcome: Recovered 01/06/2007 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Neurodermatitis		Puritis.	Cessation of Zoloft.

Medicine Details:

KALMA (Other drug) **Reason:**
0.3 Milligram
Batch: **Started:** **Stopped:**

ZOLADEX IMPLANT (Other drug) **Reason:**
Batch: **Started:** L TERM **Stopped:**

COVERSYL (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

LIPITOR (Other drug) **Reason:**
10.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

onset of itch 2-3 months after starting zoloft =- resolved on cessation within 1 week.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230204 **Seq:** 1 **Gender:** M
Reported: 25/06/2007 **Weight:** 80.00
Hospitalisation: Required a visit to the doctor **Age:** 73
Onset Date: 01/05/2006 **DOB:** 20/08/1932
Outcome: Recovered 01/06/2007 **Causality:** Causality probable

Reaction Detail

Medicine Details:

WARFARIN SODIUM (Other drug)			**Reason:**		
	2.5	Milligram	Daily		
Batch:	**Started:**		L TERM	**Stopped:**	
ZOLOFT (Suspected)			**Reason:**	Depression	
Tablet	50.0	Milligram	Daily		Oral
Batch:	**Started:**	15/11/2005		**Stopped:**	18/05/2007

Laboratory Investigations:

Additional Information:
onset of itch 2-3 months after starting zoloft =- resolved on cessation within 1 week.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230310 **Seq:** 1
Reported: 28/06/2007
Hospitalisation: Admitted to hospital
Onset Date: 17/04/2007
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 36
DOB: 24/08/1970
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pustular psoriasis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Suspected) **Reason:**
Tablet 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230506 **Seq:** 1 **Gender:** U
Reported: 02/07/2007 **Weight:** 80.00
Hospitalisation: **Age:** 52
Onset Date: 24/07/2007 **DOB:** 04/10/1954
Outcome: Recovered 26/07/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise	Caused or prolonged inpatient hospitalisation	Unwell, palpitations, sweating, stiff neck, nystagmus, increased tone and reflexes in all limbs, clonus both feet, heart rate 156, blood pressure 100/55, temperture 37.2, sertonin syndrome	Midazalam, IV Fluids, chlorpromazine, IV cyproheptadine
Clonus	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 25/07/2007

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 24/07/2007 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230506 **Seq:** 1 **Gender:** U
Reported: 02/07/2007 **Weight:** 80.00
Hospitalisation: **Age:** 52
Onset Date: 24/07/2007 **DOB:** 04/10/1954
Outcome: Recovered 26/07/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperreflexia	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 25/07/2007

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 24/07/2007 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230506 **Seq:** 1 **Gender:** U
Reported: 02/07/2007 **Weight:** 80.00
Hospitalisation: **Age:** 52
Onset Date: 24/07/2007 **DOB:** 04/10/1954
Outcome: Recovered 26/07/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nystagmus	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		
Serotonin syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 25/07/2007

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 24/07/2007 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230506 **Seq:** 1 **Gender:** U
Reported: 02/07/2007 **Weight:** 80.00
Hospitalisation: **Age:** 52
Onset Date: 24/07/2007 **DOB:** 04/10/1954
Outcome: Recovered 26/07/2007 **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction) **Reason:** Depression
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 25/07/2007

TRAMADOL HYDROCHLORIDE (Interaction) **Reason:** Pain
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 24/07/2007 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230529 **Seq:** 1
Reported: 03/07/2007
Hospitalisation:
Onset Date: 28/06/2007
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 21
DOB: 01/07/1985
Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation delayed	Incapacity/disability		

Medicine Details:

ZOLOFT (Suspected) **Reason:** Depression

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 21/06/2007 **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230610 **Seq:** 1 **Gender:** M
Reported: 04/07/2007 **Weight:** 0.00
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 05/07/1979
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular Mitral valve incompetence Sinus tachycardia		Left ventricular dilatation, mitral regurgitation, sinus tachycardia.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CLOPINE (Suspected) **Reason:**
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 14/12/2005 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/07/2007	Echocardiogram				An echocardiogram conducted on 18/05/2007 revealed mild left ventricular dilatation with normal thickness, normal systolic function at increased heart rate and normal left atrial size. The mitral valve was normal in appearance and function however some regurgitation was noted. The tricuspid aortic valve was normal in function and size with no significant regurgitation.

Additional Information:

Patient had history of alcohol abuse (mainly) binge drinking.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230675 **Seq:** 1 **Gender:** F
Reported: 05/07/2007 **Weight:** 78.00
Hospitalisation: **Age:** 33
Onset Date: 02/06/2007 **DOB:** 07/04/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response unexpecte		Previously prescribed Zoloft 100mg. Dispensed generic Chemmart sertraline 100mg, became nauseous after each dose progressively getting worse.	

Medicine Details:

Chem Mart Sertraline (Suspected) **Reason:**
100.0 Milligram Daily
Batch: 635 Exp 07/09 **Started:** 02/06/2007 **Stopped:** 05/06/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230822 **Seq:** 1 **Gender:** M
Reported: 10/07/2007 **Weight:** 0.00
Hospitalisation: **Age:** 59Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare		Experienced vivid nightmares.	Ceased GenRx sertraline

Medicine Details:

GenRx Sertraline (Suspected) **Reason:** Depression

Tablet 50.0 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 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230824 **Seq:** 1 **Gender:** F
Reported: 10/07/2007 **Weight:** 0.00
Hospitalisation: **Age:** 57Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare		Experienced vivid nightmares and daytime depression.	

Medicine Details:

GenRx Sertraline (Suspected) **Reason:** Depression

Tablet 50.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

CERT(rechall).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2002 To 31 Dec 2059 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 230966 **Seq:** 1 **Gender:** F
Reported: 16/07/2007 **Weight:** 58.00
Hospitalisation: **Age:** 14
Onset Date: 18/02/2007 **DOB:** 02/05/1992
Outcome: Recovered 19/02/2007 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Recent suicidal ideation in patient with no past history.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 05/02/2007 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information: