THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 160403 **Seq:** 1
Reported: 04/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 31/12/2000
Outcome: Recovered

Gender: M
Weight:
Age: A2
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder Dehydration Delirium Diarrhoea Hypotension Leukocytosis Pneumonia Pyrexia Tachycardia			Patient was hospitalised.

Medicine Details:

EPILIM (Other drug) **Reason:**
500.0 Milligram Daily
Batch: **Started:** **Stopped:**

VENLAFAXINE HYDROCHLORIDE (Other drug) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 01/12/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				The patient also had a eosinophilic cationic protein of 63.5 (range 0 - 15)
	Other data				Enlarged heart on echocardiogram. 22/12/00 echocardiogram left ventricular dilatation moderate to severe. 27/12/00 echocardiogram normal.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 160404 **Seq:** 1
Reported: 04/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 31/12/2000
Outcome: Recovered

Gender: M
Weight:
Age: 47
DOB: 02/12/1953
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			Treated with gliclazide

Medicine Details:

CLOZARIL (Suspected) **Reason:**
200.0 Milligram Daily
Batch: **Started:** 04/09/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 160532 **Seq:** 1 **Gender:** M
Reported: 12/01/2001 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: 09/01/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal impairment Thrombocytopenia			

Medicine Details:

PHENYTOIN SODIUM (Suspected) **Reason:** Other&unspecified epilepsy
Injection 0.0 Intravenous
Batch: **Started:** 05/01/2001 **Stopped:** 06/01/2001

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
300.0 Milligram Daily
Batch: **Started:** 01/01/1997 **Stopped:** 05/01/2001

CEFTRIAXONE (Suspected) **Reason:** Otr&nos infec&parasit diseases
4.0 Gram Daily
Batch: **Started:** 05/01/2001 **Stopped:** 06/01/2001

GENTAMICIN SULPHATE (Suspected) **Reason:** Otr&nos infec&parasit diseases
240.0 Milligram Daily
Batch: **Started:** 04/01/2001 **Stopped:** 05/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		04/01/2001	23	
	ALT = SGPT		09/01/2001	4540	
	AST = SGOT		04/01/2001	49	
	AST = SGOT		09/01/2001	1062	
	Creatinine		04/01/2001	194	
	Creatinine		09/01/2001	392	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 160532 **Seq:** 1
Reported: 12/01/2001
Hospitalisation:
Onset Date: 09/01/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 44Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

PARACETAMOL (Suspected)		**Reason:**	Pyrexia of unknown origin
	4.0 Gram	Daily	
Batch:	**Started:** 04/01/2001		**Stopped:** 08/01/2001
PENICILLIN NOS (Suspected)		**Reason:**	Otr&nos infec&parasit diseases
Injection	3.6 Gram	Daily	Intravenous
Batch:	**Started:** 06/01/2001		**Stopped:**

Laboratory Investigations:

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 160724 **Seq:** 1 **Gender:** M
Reported: 16/01/2001 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Basal cell carcinoma		Large basal cell carcinoma	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	400.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 160783 **Seq:** 1
Reported: 19/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 15/05/2000
Outcome: Not yet recovered

Gender: F
Weight:
Age: 36
DOB: 20/08/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Albuminuria			
Cardiac arrest			
Dyspnoea			
Eosinophilia			
Haematuria			
Headache			
Hepatomegaly			
Hepatosplenomegaly			
Leukocytosis			
Myalgia			

Medicine Details:

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

CLOZAPINE (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Ct showed hepatomegaly.
	Pharmacokinetics				Clozapine level was >1000ng/ml.

Additional Information:

Reactions also included diarrhoea, fever, malaise and sweats. patient also taking valproate. patient was a smoker of >20 years with 40 cigs per day.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 160783 **Seq:** 1
Reported: 19/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 15/05/2000
Outcome: Not yet recovered

Gender: F
Weight:
Age: 36
DOB: 20/08/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Pulmonary hypertension			Steroids were given. cpr, adrenaline, defibrillation & kci given for vf arrest patient was hospitalised.

Medicine Details:

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

CLOZAPINE (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Reactions also included diarrhoea, fever, malaise and sweats. patient also taking valproate. patient was a smoker of >20 years with 40 cigs per day.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 160831 **Seq:** 1
Reported: 22/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/01/2001
Outcome: Recovered

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

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ketosis Hyperventilation Thirst Weight increased		Diabetic ketoacidosis	Patient admitted to hospital icu. insulin infusion given.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 01/09/1998 **Stopped:** 12/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Glucose 36, ph on admission 6.9

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year. no previous history of diabetes.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161026 **Seq:** 1
Reported: 05/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 21/12/2000
Outcome: Unknown

Gender: F
Weight:
Age: 16
DOB: 18/04/1984
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mouth ulceration Chest pain Electrocardiogram abnormal Neutropenia Tachycardia		Ulcerations in top of mouth.	Patient was admitted to hospital

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 01/08/2000 **Stopped:** 31/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				The latest neutrophil count was recorded as 1.43 and the last three white blood cell counts were 3.9, 3.7, 3.3 (3.3 being the latest result).

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161028 **Seq:** 1
Reported: 22/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 13/12/2000
Outcome: Recovered

Gender: M
Weight:
Age: 36
DOB: 25/12/1963
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Patient was hospitalised, clozaril was ceased and commenced olanzapine.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 24/09/1996 **Stopped:** 13/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		15/09/1996	3.7	
	Neutrophils		13/12/2000	1.1	
	Neutrophils		27/12/2000	2.90	
	Neutrophils		15/12/2000	5.50	
	White blood cells		15/09/1996	5.2	
	White blood cells		13/12/2000	3.7	
	White blood cells		15/12/2000	7.40	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161028 **Seq:** 1
Reported: 22/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 13/12/2000
Outcome: Recovered

Gender: M
Weight:
Age: 36
DOB: 25/12/1963
Causality: Causality probable

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 24/09/1996 **Stopped:** 13/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		27/12/2000	5.40	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161029 **Seq:** 1
Reported: 22/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 31/12/2000
Outcome: Not yet recovered

Gender: M
Weight:
Age: 21
DOB: 27/03/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain		Abdominal discomfort	
Eosinophilia			Ceased clozaril, patient was hospitalised.
Hepatic function abnormal			

Medicine Details:

LITHIUM CARBONATE (Other drug)			**Reason:**	
Tablet	375.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
Tablet	175.0	Milligram	Daily	Oral
Batch:	**Started:** 01/11/2000		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Alanine transaminase of 250 (usual baseline 25, upper limit of the usual reference range 50); alt increased to mid 400s; also raised gamma gt.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161031 **Seq:** 1 **Gender:** M
Reported: 22/01/2001 **Weight:**
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 10/10/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Left ventricular failure Cardiomyopathy		Left ventricular hypertrophy	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 13/10/1998 **Stopped:** 20/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Echocardiogram 09/11/2000: left ventricular hypertrophy of moderate severity left ventricular function is significantly reduced. left ventricular ejection fraction is 40% (normal 60%). possible cardiomyophathy

Additional Information:

Patient experienced symptoms 2 years after commencing clozaril.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161032 **Seq:** 1 **Gender:** M
Reported: 22/01/2001 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 09/11/2000 **DOB:** 21/04/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Echocardiogram changes	Ceased clozaril

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 22/11/1994 **Stopped:** 16/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				Routine echocardiogram performed on 9/11/00 revealed changes.

Additional Information:

Patient was also taking sodium valproate, atenolol, clonazepam. patient experienced symptoms 6 years after commencing clozaril.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161039 **Seq:** 1 **Gender:** M
Reported: 16/01/2001 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 17/09/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Low platelet count	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 06/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms 1 year after commencing clozaril.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161088 **Seq:** 1 **Gender:** M
Reported: 22/01/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 28/04/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Macular rash on body.	Treated with claratyne for 5 days.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 18/08/2000 **Stopped:** CONTIN

COGENTIN (Suspected) **Reason:**
Tablet 2.0 Milligram Daily Oral
Batch: **Started:** 01/09/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161090 **Seq:** 1 **Gender:** M
Reported: 18/01/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 31/12/2000 **DOB:** 06/10/1979
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased Hypercholesterolaemia		Significant weight gain over the last 12 months.	Clozaril dose had been reduced from 600mg to 350mg daily.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** 01/07/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Elevated cholesterol levels.

Additional Information:

Patient has gained 22kg. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161098 **Seq:** 1
Reported: 31/01/2001
Hospitalisation: Admitted to hospital
Onset Date: 22/01/2001
Outcome: Recovered

Gender: M
Weight:
Age: 44
DOB: 27/11/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pain		Stabbing pain down the left arm.	
Pericarditis		Suspected pericarditis.	
Chest pain			Patient admitted. given paracetamol.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 325.0 Milligram Daily Oral

Batch: **Started:** 07/07/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had a history of stabbing pain down his left arm over the previous week.

Report Details:

Case Number: 161100 **Seq:** 1 **Gender:** F
Reported: 31/01/2001 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 29/06/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection Anaemia neonatal Leukopenia		Chest infection.	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 0.0 Daily Oral
Batch: **Started:** 01/01/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				Baby rk (date of birth 29 jun 2000) had a clozapine level at birth of 123(?)/l mother had level of 316(?)/l (units were not provided).

Additional Information:

Patient taking clozaril therapy experienced giving birth to a baby who was 5 weeks premature. the baby had very low haemoglobin and white blood cells at birth and required a transfusion at 14 days. amitted to hospital with ongong chest infection and white blood cells in urine and perhaps requiring another blood transfusion. relevant history - 2 years ago the mother gave birth to a healthy baby while taking clozaril. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161171 **Seq:** 1 **Gender:** M
Reported: 31/01/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 19/01/2001 **DOB:** 03/03/1943
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			Date of death 19.1.01.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	300.0 Milligram	Daily	Oral

Batch: **Started:** 14/09/2000 **Stopped:** 19/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161182 **Seq:** 1 **Gender:** F
Reported: 05/02/2001 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: 22/01/2001 **DOB:** 29/01/1958
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope Leukocytosis		Found collapsed outside back door.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 01/07/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	2.0 - 8.0	22/01/2001	14.43	

Additional Information:

Patient also taking citalopram and phenergan. the patient was rousable after 3 minutes. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161183 **Seq:** 1 **Gender:** M
Reported: 05/02/2001 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 31/01/2001 **DOB:** 23/05/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Neuroleptic malignant syndrome Pancytopenia Renal impairment Syncope			Treated with noradrenaline and vasopressin at high doses. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 475.0 Milligram Daily Oral
Batch: **Started:** 01/09/2000 **Stopped:** 28/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase				Creatinine kinase approximately 700.
	Haemoglobin				Haemoglobin 2.2.
	Platelets				Platelets 27.
	White blood cells				Wbc 2.6

Additional Information:

Patient also taking haloperidol and lithium. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161339 **Seq:** 1
Reported: 07/02/2001
Hospitalisation: Admitted to hospital
Onset Date: 25/01/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 30/03/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Delirium Hallucination Leukopenia Neutropenia Pyrexia			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 325.0 Milligram Daily Oral

Batch: **Started:** 23/10/2000 **Stopped:** 26/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		23/10/2000	5.4	
	Neutrophils		24/01/2001	0.9	
	Neutrophils		25/01/2001	0.30	
	White blood cells		23/10/2000	7.5	
	White blood cells		24/01/2001	1.8	
	White blood cells		25/01/2001	1.50	

Additional Information:

Sequelae: this patient experienced mild delirium, auditory hallucinations and disorientation 14 days after discontinuing clozaril on 26/1/01.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161340 **Seq:** 1 **Gender:** M
Reported: 07/02/2001 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 31/01/2001 **DOB:** 12/04/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Chest pain Melaena		Pain radiating down left arm.	Clozaril withheld.

Medicine Details:

EPILIM (Other drug) **Reason:**
500.0 Milligram Daily
Batch: **Started:** **Stopped:**

OLANZAPINE (Other drug) **Reason:**
15.0 Milligram Daily
Batch: **Started:** **Stopped:** 06/12/2000

CLOZARIL (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 05/12/2000 **Stopped:** 28/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred 7 weeks after starting clozaril. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161341 **Seq:** 1 **Gender:** F
Reported: 07/02/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 11/12/2000 **DOB:** 11/09/1979
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Salivary hypersecretion Somnolence			Coversyl

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 01/08/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				11/12/00 - cardiac echocardiogram: mild left ventricular systolic dysfunction borderline right ventricular function.

Additional Information:

The patient experienced reaction approximately 2 years and 4 months after commencing clozaril therapy. the dose state date for clozaril is not necessarily accurated but indicates it was commenced sometime in august 1998.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161342 **Seq:** 1 **Gender:** M
Reported: 07/02/2001 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 07/12/2000 **DOB:** 08/12/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Coversyl

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	500.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/08/1998		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				07/12/00: cardiac echocardiogram showed global biventricular systolic dysfunction consistent with a cardiomyopathy

Additional Information:

The patient experienced reaction approximately 2 years and 4 months after comm encing clozaril. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161343 **Seq:** 1 **Gender:** M
Reported: 07/02/2001 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 08/01/2001 **DOB:** 28/01/1972
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Tachycardia			

Medicine Details:

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

HALOPERIDOL (Other drug) **Reason:**
1.5 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

BENZTROPINE MESYLATE (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray Electrocardiograph				01/2001: chest x ray did not detect any abnormalities (nad) Dec 2000: electrocardiogram showed sinus tachycardia 08/01/2001: cardiac echocardiogram showed mild global ventricular systolic dysfunction.

Additional Information:

The patient experienced reaction at least 2 years and 2 months after commencin g clozaril. the dosage start date is not accurate but indicates that start occurred sometime during the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161344 **Seq:** 1 **Gender:** M
Reported: 07/02/2001 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 10/11/2000 **DOB:** 05/01/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Tachycardia			

Medicine Details:

CLONAZEPAM (Other drug) **Reason:**
0.5 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 01/11/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest x ray did not detect any abnormalities (nad).
	Electrocardiograph				31/08/2000: ecg showed sinus tachycardia, rightward a x 15, else normal. 04/09/2000: ecg: both global and segmental impairement of left ventricular systolic function.

Additional Information:

Patient experienced reaction approximately 3 years after commencing clozaril. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161421 **Seq:** 1
Reported: 12/02/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/02/2001
Outcome: Unknown

Gender: F
Weight:
Age: 46
DOB: 07/08/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Confusional state Dizziness Sepsis		Temp 39 c degrees	Patient admitted to hospital

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet	300.0 Milligram	Daily	Oral	
Batch:	**Started:** 11/01/2001		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		11/01/2001	5.0	
	Neutrophils		30/01/2001	8.0	
	Neutrophils		04/02/2001	6.1	
	White blood cells		11/01/2001	8.1	
	White blood cells		30/01/2001	11.5	
	White blood cells		04/02/2001	8.2	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161422 **Seq:** 1 **Gender:** M
Reported: 12/02/2001 **Weight:**
Hospitalisation: **Age:** 18
Onset Date: 29/01/2001 **DOB:** 29/08/1982
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Treated with sodium valproate

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
450.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 04/12/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Clozaril plasma level is 250

Additional Information:

Reaction occurred 8 weeks after commencing clozaril.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161481 **Seq:** 1 **Gender:** M
Reported: 14/02/2001 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: 01/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Opisthotonus Dystonia		Involved hyperexternal of back, trunk. Slow onset several weeks after starting clozapine	

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
250.0 Milligram Daily
Batch: **Started:** 09/03/2000 **Stopped:** 02/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

P/h of diskinesia on risperidone.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161754 **Seq:** 1 **Gender:** F
Reported: 24/01/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 11/12/2000 **DOB:** 11/09/1979
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Urgent cardiology assessment. required a visit to doctor.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
500.0 Milligram Daily
Batch: **Started:** 01/08/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Cardiac echo 11/12/00: mild global left ventricular systolic dysfunction. borderline right ventricular function.
	Radiololgy				Cxr/ecg - nad asymptomatic for cardiac problems

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161755 **Seq:** 1 **Gender:** M
Reported: 24/01/2001 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 07/12/2000 **DOB:** 08/12/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Urtgent cardioligy assessment. required a visit to doctor.

Medicine Details:

CLONAZEPAM (Other drug)		**Reason:**	
	0.5 Milligram	As necessary	
Batch:	**Started:**	**Stopped:**	CONTIN
EPILIM (Other drug)		**Reason:**	
	1.0 Gram	Daily	
Batch:	**Started:**	**Stopped:**	CONTIN
CLOZAPINE (Suspected)		**Reason:**	Unspecified schizophrenia
	500.0 Milligram	Daily	
Batch:	**Started:** 01/08/1998	**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Cardiac echo (07/12/00): global biventricular systolic dysfunction consistent with a cardiomyopathy

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161756 **Seq:** 1 **Gender:** M
Reported: 24/01/2001 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 10/11/2000 **DOB:** 05/01/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Urgent cardiology assessment. required a visit to doctor.

Medicine Details:

CLONAZEPAM (Other drug) **Reason:**
0.5 Milligram As necessary
Batch: **Started:** **Stopped:** CONTIN

CLOZAPINE (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 01/11/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Cxr - (04/09/00) - nad
	Electrocardiograph				Ecg- 31/08/00 - sinus tachycardia, rightward a x 1s, else normal.
	Other data				Cardiac echo: both global and segmental impairement of left ventricular systolic function.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 161811 **Seq:** 1 **Gender:** U
Reported: 22/02/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162183 **Seq:** 1 **Gender:** M
Reported: 24/01/2001 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 08/01/2001 **DOB:** 28/01/1972
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Tachycardia		Asymptomatic of cardiac illness	Urgent cardiology assessment. required a visit to doctor.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 01/11/1998 **Stopped:** CONTIN

HALOPERIDOL (Suspected) **Reason:**
1.5 Milligram Daily
Batch: **Started:** 01/11/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph Other data				Ecg 12/00 - sinus tachycardia Cardiac echo (08/01/01): mild global left ventricular systolic dysfunction.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162235 **Seq:** 1
Reported: 05/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 10/02/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 33
DOB: 23/05/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Blood creatine phosphokinase incr Encephalopathy Pyrexia Syncope		Unconscious for approximately two weeks.	Patient was admitted into the intensive care unit.

Medicine Details:

HALOPERIDOL (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:** 09/02/2001

CLOZARIL (Suspected) **Reason:**
Tablet 475.0 Milligram Daily Oral
Batch: **Started:** 22/09/1998 **Stopped:** 10/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162236 **Seq:** 1 **Gender:** M
Reported: 05/03/2001 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Hyperventilation		Heart rate 140 beats per minute.	 Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/01/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162264 **Seq:** 1 **Gender:** M
Reported: 02/03/2001 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: 31/12/1993 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Necrosis ischaemic		Bowel necrosis.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 175.0 Milligram Daily Oral

Batch: **Started:** 01/01/1993 **Stopped:** 31/01/1993 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed fibrin clots / microemboli in the blood vessels supplying the cecum. - the date of onset is not accurate but indicates that onset occurred sometime during the year. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162265 **Seq:** 1 **Gender:** M
Reported: 02/03/2001 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 02/09/1962
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Non-insulin dependent diabetes mellitus.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** 31/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This is the fourth of four patients. the dose stop date for clozaril is not accurate but indicates the drug was stopped sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162266 **Seq:** 1 **Gender:** U
Reported: 02/03/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Non-insulin dependent diabetes mellitus.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This is the third of four patients.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162267 **Seq:** 1 **Gender:** U
Reported: 02/03/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Non-insulin dependent diabetes mellitus.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This is the second of four patients.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162268 **Seq:** 1 **Gender:** U
Reported: 02/03/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Non-insulin dependent diabetes mellitus.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This is the first of four patients.

Report Details:

Case Number: 162290 **Seq:** 1 **Gender:** M
Reported: 06/03/2001 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 28/08/2000 **DOB:** 30/06/1972
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Apnoea Sleep disorder		Suspected sleep apnoea.	Measures taken included consulting a sleep specialist and being observed overnight in a sleep clinic.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 11/02/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data Serum drug level				The results of the inital assessment at the sleep clinic showed an apnoea hypopnoea index of 23, minimum saturation of 86.6% with moderate snoring. Clozaril results reveal clozaril levels are within normal range: serum clozapine = 280 mcg/l; norclozapine = 452 mcg/l (29/1/01).

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162746 **Seq:** 1
Reported: 15/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/03/2001
Outcome: Unknown

Gender: U
Weight:
Age: 52Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bronchospasm Fatigue Pallor Pyrexia			

Medicine Details:

FUSIDIC ACID (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 01/11/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		06/03/2001	5.8	
	White blood cells		06/03/2001	6.9	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162747 **Seq:** 1 **Gender:** M
Reported: 19/03/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 19/02/2001 **DOB:** 03/09/1979
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Gastritis Orthostatic hypotension Tachycardia			Required a visit to doctor.

Medicine Details:

HALOPERIDOL (Other drug) **Reason:**
3.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 01/04/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Echocardiogram showed shortening fraction of between 22-27%.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162812 **Seq:** 1
Reported: 19/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 12/03/2001
Outcome: Recovered

Gender: F
Weight:
Age: 25
DOB: 22/11/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation Convulsion Myalgia		Reduced bowel motility.	 Patient was hospitalised.

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 1.0 Gram Daily Oral
Batch: **Started:** 01/02/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Abdominal x-ray revealed intestinal faecal content and enloarged bowel. all other parameters normal.
	Serum drug level				12/3/01: clozapine plasma level of 2106ng/ml

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162830 **Seq:** 1 **Gender:** M
Reported: 21/03/2001 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 03/03/2001 **DOB:** 02/11/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Reaction occuured 3 weeks after starting clozaril	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 10/02/2001 **Stopped:** 03/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162831 **Seq:** 1 **Gender:** M
Reported: 21/03/2001 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 02/12/1951
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
0.0 Oral
Batch: **Started:** 01/01/1994 **Stopped:** 28/04/1999

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
400.0 Milligram Daily Oral
Batch: **Started:** 08/07/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had pre-existing cardiomyopathy prior to starting clozaril. the dose start and dose stop date of the earlier clozaril dose is not necessarily accurate but indicates the drug was started and stopped sometime in the months stated.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162832 **Seq:** 1
Reported: 21/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 10/03/2001
Outcome: Unknown

Gender: M
Weight:
Age: 55
DOB: 10/11/1945
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Pathological fracture			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 500.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking sodium valproate, clexane, voltaren. hx of pre-existing epilepsy.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162852 **Seq:** 1
Reported: 15/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 03/03/2001
Outcome: Recovered

Gender: F
Weight:
Age: 62
DOB: 29/11/1938
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 23/10/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 162927 **Seq:** 1 **Gender:** F
Reported: 23/03/2001 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 29/12/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Ventricular dysfunction	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 04/08/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163047 **Seq:** 1
Reported: 27/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 27/01/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 33
DOB: 25/05/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Neuroleptic malignant syndrome Syncope	Life threatening	Multi organ failure.	Life support, icu admission, intubation-> tracheo, iv fluids,/electrolyte balance. patient in icu 42 days now in medical ward.

Medicine Details:

CLOZAPINE (Suspected)		**Reason:**	Unspecified schizophrenia
	475.0 Milligram	Daily	
Batch:	**Started:** 10/11/1998		**Stopped:** 27/01/2001
HALOPERIDOL (Suspected)		**Reason:**	Schizophrenia
	5.0 Milligram	Daily	
Batch:	**Started:** 01/09/2000		**Stopped:** 27/01/2001
LITHIUM CARBONATE (Suspected)		**Reason:**	Schizophrenia
	1.0 Gram	Daily	
Batch:	**Started:** 01/09/2000		**Stopped:** 27/01/2001
BENZTROPINE MESYLATE (Suspected)		**Reason:**	Schizophrenia
	2.0 Milligram	Daily	
Batch:	**Started:** 01/09/2000		**Stopped:** 28/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but indicates the drug was started sometime in the month. sequelae: evidence of brain damage.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163118 **Seq:** 1
Reported: 28/03/2001
Hospitalisation: Admitted to hospital
Onset Date: 10/03/2001
Outcome: Recovered

Gender: M
Weight:
Age: 27
DOB: 21/02/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis Priapism			Patient was hospitalised and required surgery to reduce priapism.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 07/02/2000 **Stopped:** 17/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		20/03/2001	11.9	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163321 **Seq:** 1 **Gender:** F
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 28/03/2001 **DOB:** 06/09/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis Pneumonia Pyrexia			Panadol and rulide

Medicine Details:

TIMOLOL MALEATE EYE DROPS (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 25/02/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest x-ray: the mediastinal contours are otherwise normal. there is fairly extensive peribronchial patchy shadowing in both lower zones which is probably reflective of active/acute pathology, but comparison with any previous chest x-rays would be optimal. there is also slight blunting of the lateral costo-phrenic angles in keeping with pleural thickening or small effusions. assuming

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163321 **Seq:** 1 **Gender:** F
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 28/03/2001 **DOB:** 06/09/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

TIMOLOL MALEATE EYE DROPS (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**			**Stopped:**
VALIUM (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**			**Stopped:**
CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	300.0	Milligram	Daily	Oral
Batch:	**Started:**	25/02/2001		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				The bibasal changes are acute it most likely reflects peribronchial infection (early bronchopneumonia?) particularly given the history of fever. radio- graphically, the differential diagnosis includes pulmonary oedema but this would seem much less likely.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163337 **Seq:** 1 **Gender:** F
Reported: 28/03/2001 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 28/11/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocythaemia		Mild-moderate essential thrombocytosis.	

Medicine Details:

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

ZOLOFT (Other drug) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/04/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the patient has a genetic history of thrombosis/gene mutation. father died of thrombosis. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163383 **Seq:** 1 **Gender:** M
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: 20/03/2001 **DOB:** 05/01/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Ceased clozaril.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 10/09/1996 **Stopped:** 22/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		10/09/1996	3	
	Neutrophils		20/03/2001	0.40	
	Neutrophils		30/03/2001	1.7	
	Neutrophils		25/03/2001	0.4	
	White blood cells		10/09/1996	4.9	
	White blood cells		20/03/2001	1.8	
	White blood cells		25/03/2001	2.1	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163383 **Seq:** 1 **Gender:** M
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: 20/03/2001 **DOB:** 05/01/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 450.0 Milligram Daily Oral

Batch: **Started:** 10/09/1996 **Stopped:** 22/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		30/03/2001	3.2	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163440 **Seq:** 1
Reported: 05/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/02/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 19/05/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension		Systolic - 180 and diastolic - 120.	Patient was hospitalised. date of recovery 22.03.01. treated with perindopril 2mg daily (initiated 21.3.01).

Medicine Details:

EPILIM (Other drug)			**Reason:**	Unspecified schizophrenia	
	1.7	Gram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
ZANTAC (Other drug)			**Reason:**		
	300.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
COGENTIN (Other drug)			**Reason:**	Prophylaxis	
	2.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN
LARGACTIL (Other drug)			**Reason:**	Unspecified schizophrenia	
	100.0	Milligram	Daily		
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of elevated blood pressure prior to clozapine however baseline blood pressure did increase once clozapine was initiated.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163440 **Seq:** 1
Reported: 05/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/02/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 19/05/1960
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
500.0 Milligram Daily
Batch: **Started:** 27/02/2001 **Stopped:** CONTIN

Laboratory Investigations:

Additional Information:

Patient has a history of elevated blood pressure prior to clozapine however baseline blood pressure did increase once clozapine was initiated.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163504 **Seq:** 1 **Gender:** F
Reported: 06/04/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence Choking Coma Constipation Salivary hypersecretion Vomiting		Bedwetting	

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	
Tablet	1.2	Gram	Daily	Oral
Batch:	**Started:**			**Stopped:**
AROPAX (Suspected)			**Reason:**	
	40.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
RISPERIDONE (Suspected)			**Reason:**	
	6.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163506 **Seq:** 1 **Gender:** M
Reported: 06/04/2001 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 16/02/1970
Outcome: Unknown **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspepsia		Belly-ache	
Dysuria		Painful passing of urine	
Hepatosplenomegaly			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
600.0 Milligram Daily
Batch: **Started:** 12/03/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient ceased clozaril and symptoms disappeared. patient restarted clozaril and symptoms reappeared.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163592 **Seq:** 1 **Gender:** F
Reported: 09/04/2001 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 28/02/2001 **DOB:** 15/06/1959
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			Patient died on march 2001. autopsy performed.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** L TERM **Stopped:** 28/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				There was no significant natural disease on either naked eye or microscopic examination, and toxicology screening was negative. a microscopic examination of tissues revealed no abnormality of the heart and no evidence of mycarditis in the sections examined.
	Other data				Direct cause of disease or condition directly leading to death: not determined

Additional Information:

The date of onset is not accurate but indicates onset sometimes in the year. the dose stop date for the drug clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163594 **Seq:** 1
Reported: 09/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 27/03/2001
Outcome: Unknown

Gender: M
Weight:
Age: 36
DOB: 30/11/1964
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium		Acute delirium.	Admitted to hospital
Drug level increased		Elevated clozapine levels	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 450.0 Milligram Daily Oral

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

AROPAX (Suspected) **Reason:**

Tablet 40.0 Milligram Daily Oral

Batch: **Started:** 07/03/2001 **Stopped:** 29/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163595 **Seq:** 1 **Gender:** M
Reported: 09/04/2001 **Weight:** 0.00
Hospitalisation: **Age:** 19
Onset Date: 30/03/2001 **DOB:** 23/11/1981
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia		Patient experienced low neutrophils and low white blood cells	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
0.0
Batch: **Started:** 02/10/2000 **Stopped:** 30/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Neutrophils		11/02/2005	1.50X10?9L	
17/12/2002	Neutrophils		11/02/2005	1.4	
17/12/2002	White blood cells		11/02/2005	2.80X10?9L	

Additional Information:

Recurred 04/06/02 on clozaril. recovered again.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163751 **Seq:** 1 **Gender:** U
Reported: 12/04/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia Myocarditis Pyrexia Tachycardia			Clozaril ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163820 **Seq:** 1 **Gender:** M
Reported: 19/04/2001 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 14/02/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Severe	Severe reactions.	Clozaril ceased.
Electrocardiogram T wave inversio	Severe		
Electrocardiogram abnormal	Severe		

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 10/02/2001 **Stopped:** 14/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg's developed t inversions, st elevation and q waves. resolved after 2/52.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163828 **Seq:** 1
Reported: 19/04/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

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

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	0.0	Oral	
Batch:	**Started:**	**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163962 **Seq:** 1 **Gender:** F
Reported: 31/01/2001 **Weight:**
Hospitalisation: **Age:** 54
Onset Date: 03/11/2000 **DOB:** 26/03/1946
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			One dose of filgrastin.

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 30/11/1994 **Stopped:** 03/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		29/11/1994	5.7	
	Neutrophils		03/11/2000	0.5	
	Neutrophils		06/11/2000	20.7	
	Neutrophils		07/12/2000	2.58	
	Neutrophils		05/12/2000	1.69	
	Neutrophils		04/12/2000	1.16	
	White blood cells		29/11/1994	8.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163962 **Seq:** 1 **Gender:** F
Reported: 31/01/2001 **Weight:**
Hospitalisation: **Age:** 54
Onset Date: 03/11/2000 **DOB:** 26/03/1946
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 30/11/1994 **Stopped:** 03/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		03/11/2000	2.3	
	White blood cells		06/11/2000	33.4	
	White blood cells		04/12/2000	3.1	
	White blood cells		05/12/2000	4.0	
	White blood cells		07/12/2000	4.9	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163964 **Seq:** 1 **Gender:** F
Reported: 07/04/2001 **Weight:**
Hospitalisation: **Age:** 66
Onset Date: 23/11/2000 **DOB:** 23/07/1934
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Ceased cloaril

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 125.0 Milligram Daily Oral
Batch: **Started:** 12/09/2000 **Stopped:** 24/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163968 **Seq:** 1 **Gender:** M
Reported: 15/04/2001 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 15/01/2001 **DOB:** 20/12/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 1.2 Gram Daily Oral
Batch: **Started:** 24/03/1997 **Stopped:** 16/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Neutrophils		23/07/2003	6.9	
17/12/2002	Neutrophils		23/07/2003	1.30	
17/12/2002	White blood cells		23/07/2003	9.9	
17/12/2002	White blood cells		23/07/2003	4.20	

Additional Information:

The patient experienced possible reoccurrence of neutropenia late in 2002, after recommencing clozaril in Nov 2002. Clozaril therapy was again discontinued and recommenced in March 2003. the outcome of the event was not provided.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163969 **Seq:** 1 **Gender:** F
Reported: 14/03/2001 **Weight:**
Hospitalisation: **Age:** 81
Onset Date: 31/01/2001 **DOB:** 27/01/1920
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 14/04/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163971 **Seq:** 1 **Gender:** M
Reported: 21/03/2001 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 28/02/2001 **DOB:** 03/10/1941
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash Anorexia Jaundice Vomiting		Rash on torso	 Clozaril ceased.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 02/01/2001 **Stopped:** 28/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking antibiotics (not specified). the date of onset is not necessarily accurate but indicates onset sometime in the month. the stop date is not necessarily accurate but indicates the drug was stopped s ometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163973 **Seq:** 1 **Gender:** M
Reported: 28/03/2001 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 28/03/2001 **DOB:** 21/04/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia Anorexia Lymphopenia			

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 12/01/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				A chest x-ray showed an area of consolidation and the diagnosis was emphysema.
	Haemoglobin				Haemoglobin level which had dropped from 12.6 to 9.7 in one month.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163974 **Seq:** 1 **Gender:** M
Reported: 21/03/2001 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 19/02/2001 **DOB:** 12/05/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Pt admitted to hospital. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 05/10/1999 **Stopped:** 19/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		29/09/1999	4.7	
	Neutrophils		19/02/2001	1.41	
	Neutrophils		20/02/2001	3.38	
	White blood cells		29/09/1999	7.9	
	White blood cells		19/02/2001	4.4	
	White blood cells		20/02/2001	6.9	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163975 **Seq:** 1
Reported: 02/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 27/02/2001
Outcome: Recovered

Gender: M
Weight:
Age: 53
DOB: 05/08/1947
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Pt hospitalised. clozaril ceased.

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 25/01/2000 **Stopped:** 27/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		13/01/2000	3.7	
	Neutrophils		27/02/2001	1.3	
	Neutrophils		02/03/2001	2.7	
	White blood cells		13/01/2000	6.9	
	White blood cells		27/02/2001	3.5	
	White blood cells		02/03/2001	4.9	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163976 **Seq:** 1 **Gender:** M
Reported: 09/04/2001 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 28/03/2001 **DOB:** 22/08/1973
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 03/04/2000 **Stopped:** 28/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		03/04/2000	3.0	Neutrophil in 2001 = 1.3, eight hours later 2.0.
	White blood cells		03/04/2000	5.4	

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163977 **Seq:** 1
Reported: 02/04/2001
Hospitalisation:
Onset Date: 19/03/2001
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 41
DOB: 17/07/1959
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia Neutropenia			Clozaril ceased

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

CLOZARIL (Suspected) **Reason:**
675.0 Milligram Daily Oral
Batch: **Started:** 19/12/2000 **Stopped:** 12/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Neutrophils		02/02/2006	2.4	
17/12/2002	Neutrophils		02/02/2006	0.7	
17/12/2002	Neutrophils		02/02/2006	0.4	
17/12/2002	Neutrophils		02/02/2006	0.3	
17/12/2002	Neutrophils		02/02/2006	1.0	
17/12/2002	Neutrophils		02/02/2006	0.6	
17/12/2002	Neutrophils		02/02/2006	0.3	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163977 **Seq:** 1
Reported: 02/04/2001
Hospitalisation:
Onset Date: 19/03/2001
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 41
DOB: 17/07/1959
Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug) **Reason:**
0.0
Batch: **Started:** L TERM **Stopped:**

CLOZARIL (Suspected) **Reason:**
675.0 Milligram Daily Oral
Batch: **Started:** 19/12/2000 **Stopped:** 12/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Neutrophils		02/02/2006	0.4	
17/12/2002	White blood cells		02/02/2006	3.6	
17/12/2002	White blood cells		02/02/2006	1.5	
17/12/2002	White blood cells		02/02/2006	1.1	
17/12/2002	White blood cells		02/02/2006	1.3	
17/12/2002	White blood cells		02/02/2006	1.2	
17/12/2002	White blood cells		02/02/2006	1.1	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163977 **Seq:** 1
Reported: 02/04/2001
Hospitalisation:
Onset Date: 19/03/2001
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 41
DOB: 17/07/1959
Causality: Causality possible

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**	L TERM	**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
	675.0 Milligram	Daily		Oral
Batch:	**Started:** 19/12/2000		**Stopped:**	12/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	White blood cells		02/02/2006	1.4	
17/12/2002	White blood cells		02/02/2006	2.0	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163978 **Seq:** 1 **Gender:** M
Reported: 12/04/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 28/03/2001 **DOB:** 10/03/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Life threatening reaction	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 20/12/2000 **Stopped:** 24/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils				Eosinophils normal throughout.
	Other data				Fractional shortening of 22%, mild left ventricular enlargement, mild global dysfunction - observed on a routine echocardiogram.
	Other data		13/12/2000	< 0.3	Troponin i levels.
	Other data		21/03/2001	< 0.3	Troponin i levels.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163978 **Seq:** 1 **Gender:** M
Reported: 12/04/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 28/03/2001 **DOB:** 10/03/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 20/12/2000 **Stopped:** 24/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				15/3/01: echocardiogram revealed mildly dilated lv with mild global systolic dysfunction; normal size la; normal size ra; normal rv size and function; morphologically normal trileaflet aortic valve; morphologically normal mitral valve; morphologically normal tricuspid valve; normal pulmonary valve. conclusion: mild global lv systolic function & normal valve function.
	Serum drug level		14/03/2001	103 MCG/L	Clozapine level

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163978 **Seq:** 1 **Gender:** M
Reported: 12/04/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 28/03/2001 **DOB:** 10/03/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 20/12/2000 **Stopped:** 24/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		21/03/2001	123	Clozapine level

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163979 **Seq:** 1 **Gender:** M
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 27/07/1973
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia			

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 14/09/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163983 **Seq:** 1 **Gender:** M
Reported: 26/04/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 09/04/2001 **DOB:** 12/03/1972
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 06/04/1999 **Stopped:** 11/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Routine electrogardiograph which showed evidence of cardiomyopathy.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 163984 **Seq:** 1 **Gender:** F
Reported: 26/04/2001 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 10/04/2001 **DOB:** 01/01/1960
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Aortic valve dis not rheumatic

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 03/04/2001 **Stopped:** 10/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Tachycardia discovered on routine echocardiogram.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164030 **Seq:** 1 **Gender:** M
Reported: 19/03/2001 **Weight:**
Hospitalisation: **Age:** 22
Onset Date: 31/12/1995 **DOB:** 24/08/1973
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neurosis			Treatment with selective serotonin re-uptake inhibitors, and exposure and response prevention treatment. reduction in the dose of clozaril.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 400.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year. the dose start date is not accurate but indicates the drug was started sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164048 **Seq:** 1 **Gender:** F
Reported: 29/03/2001 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 31/01/2001 **DOB:** 21/12/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia			
C-reactive protein increased			
Constipation			
Eosinophilia			
Lymphopenia			
Nausea			
Pyrexia			
Tachycardia			Clozaril ceased. antibiotics given
Thrombocytopenia			
Vomiting			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 12.5 Milligram Daily Oral

Batch: **Started:** 18/01/2001 **Stopped:** 01/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient ceased clozaril on 24/01/01 due to heart problems.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164123 **Seq:** 1
Reported: 30/04/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/04/2001
Outcome: Recovered

Gender: M
Weight:
Age: 55
DOB: 10/11/1945
Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction		Small bowel obstruction	Iv fluids. pt hospitalised. clozaril and phenytoin ceased for 4 days

Medicine Details:

PHENYTOIN SODIUM (Other drug) **Reason:** Other&unspecified epilepsy
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 01/11/2000 **Stopped:** 10/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Abdomen X-ray				X-ray of abdomen - pseudo small bowel obstruction.

Additional Information:

Patient has experienced 2 episodes of small bowel obstruction whilst receiving clozaril. patient was expected to be recommenced on clozaril on 14/04/01. the date of onset is not necessarily accurate but indicates onset sometime in april 2001. the dose start date is not necessarily accurate but indicates the drug was started sometime in november 2000.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164125 **Seq:** 1 **Gender:** M
Reported: 30/03/2001 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 09/05/1995 **DOB:** 04/01/1955
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			G-csf. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

0.0

Batch: **Started:** **Stopped:** 7M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164182 **Seq:** 1
Reported: 03/05/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 27
DOB: 23/10/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Pyrexia Somnolence			 Pt hospitalised

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 0.0 Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164366 **Seq:** 1 **Gender:** F
Reported: 09/05/2001 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: **DOB:** 24/10/1948
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 325.0 Milligram Daily Oral
Batch: **Started:** 28/04/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164369 **Seq:** 1 **Gender:** F
Reported: 09/05/2001 **Weight:**
Hospitalisation: **Age:** 44Y
Onset Date: 30/04/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Elevated clozapine plasma levels.	
Tachycardia	Required Specialist Consultation	Mild benign tachycardia.	
Cardiomegaly	Required Specialist Consultation	Mild left ventricular hypertrophy.	
Palpitations			

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		26/03/2001	1300	Clozpaine levels.
	Serum drug level		23/04/2001	1500	Clozpaine levels.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164372 **Seq:** 1 **Gender:** F
Reported: 30/04/2001 **Weight:**
Hospitalisation: **Age:** 56
Onset Date: **DOB:** 12/12/1944
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
325.0 Milligram Daily
Batch: **Started:** 15/08/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164399 **Seq:** 1 **Gender:** M
Reported: 10/05/2001 **Weight:** 61.00
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Malaise			Clozapine dose reduced to 400mg. started on tritace.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
450.0 Milligram Daily
Batch: **Started:** 26/07/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Echo - 22/03/01: mild global reduction in l. ventricular systolic function (ej ection fraction 458). clozapine dose reduced. started on tritace --> normal echo on 18/04/01.

Additional Information:

Since clozapine reduction patient is more psychotic.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164456 **Seq:** 1 **Gender:** M
Reported: 11/05/2001 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 16/02/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164457 **Seq:** 1 **Gender:** M
Reported: 11/05/2001 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 06/04/2001 **DOB:** 20/06/1969
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Confusional state Convulsion Hyponatraemia Polydipsia Rhabdomyolysis			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 01/12/2000 **Stopped:** 06/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Creatinine kinase levels up to 85000.

Additional Information:

Report number 167107 is duplicate of this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164513 **Seq:** 1
Reported: 14/05/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age: 37
DOB: 23/02/1964
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope Coma		Collapse into unconsciousness.	Patient is in the hospital intensive care unit.

Medicine Details:

WARFARIN SODIUM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 28/03/2001

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 05/08/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions occurred 3 years and 9 months after commencing clozaril. the dose stop date for warfarin in not necessarily accurate but indicates that the drug was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164514 **Seq:** 1
Reported: 14/05/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight:
Age: 22
DOB: 20/06/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			Patient admitted to hospital for monitoring. clozaril ceased.

Medicine Details:

MIXTARD 30/70 (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 30/06/1998 **Stopped:** 10/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets				Platelets: 30.
	Troponin				Tropinin: 0.3.

Additional Information:

The patient had a similar episode 12 months ago.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164789 **Seq:** 1 **Gender:** M
Reported: 23/05/2001 **Weight:** 142.00
Hospitalisation: **Age:** 26
Onset Date: 11/05/2001 **DOB:** 22/04/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Acute onset of fever.	Patient was reviewed by a physician, who ordered blood screening. clozaril discontinued temporarily.
Tremor		Tremulousness.	
Productive cough		White sputum.	
C-reactive protein increased			
Cough			
Headache			
Leukocytosis	Required Specialist Consultation		

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
0.5 Milligram Daily
Batch: **Started:** 09/05/2001 **Stopped:**

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

QUILONUM SR (Other drug) **Reason:**
1.3 Gram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 26/04/2001 **Stopped:** 12/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	C-Reactive Protein		12/05/2001	40MG/L	
	Erythrocyte [illegible]		12/05/2001	27MM/H	
	Neutrophils		12/05/2001	13.3X10?9L	
	White blood cells		12/05/2001	14.9X10?9L	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164789 **Seq:** 1 **Gender:** M
Reported: 23/05/2001 **Weight:** 142.00
Hospitalisation: **Age:** 26
Onset Date: 11/05/2001 **DOB:** 22/04/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pain Red blood cell sedimentation rate i Thrombocytopenia Vomiting	Required Specialist Consultation		

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
0.5 Milligram Daily
Batch: **Started:** 09/05/2001 **Stopped:**

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

QUILONUM SR (Other drug) **Reason:**
1.3 Gram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 26/04/2001 **Stopped:** 12/05/2001

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164790 **Seq:** 1 **Gender:** F
Reported: 23/05/2001 **Weight:**
Hospitalisation: **Age:** 60
Onset Date: 28/04/2001 **DOB:** 21/11/1940
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis Pneumonia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
400.0 Milligram Daily
Batch: **Started:** 31/10/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		28/10/1994	8.1	
	Neutrophils		21/03/2001	4.40	
	Neutrophils		18/04/2001	11.80	
	Neutrophils		14/06/2001	19.3	
	Neutrophils		13/06/2001	14.4	
	Neutrophils		16/05/2001	6.4	
	White blood cells		28/10/1994	11.8	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164790 **Seq:** 1 **Gender:** F
Reported: 23/05/2001 **Weight:**
Hospitalisation: **Age:** 60
Onset Date: 28/04/2001 **DOB:** 21/11/1940
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
400.0 Milligram Daily
Batch: **Started:** 31/10/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		21/03/2001	9.30	
	White blood cells		18/04/2001	16.9	
	White blood cells		16/05/2001	8.2	
	White blood cells		13/06/2001	19.5	
	White blood cells		14/06/2001	22.2	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164791 **Seq:** 1 **Gender:** M
Reported: 23/05/2001 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 09/05/2001 **DOB:** 08/11/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 01/01/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		04/07/2000	9.9X10?9/L	
	Neutrophils		09/05/2001	18X10?9/L	
	White blood cells		04/07/2000	13.6X10?9L	
	White blood cells		09/05/2001	23.7X10?9L	

Additional Information:

The dose start date for clozaril is not accurate but indicates clozaril was started sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164908 **Seq:** 1 **Gender:** M
Reported: 28/05/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 19/03/2001 **DOB:** 30/09/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 175.0 Microgram Daily Oral

Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		19/03/2001	63	
	Bilirubin		19/03/2001	37	

Additional Information:

The dose start date is not accurate but indicates the drug was started sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 164954 **Seq:** 1
Reported: 28/05/2001
Hospitalisation: Treated in outpatient department only.
Onset Date: 14/04/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 26
DOB: 05/01/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Night sweats	
C-reactive protein increased			
Eosinophilia			Patient presented to casualty 3 days in a row. clozaril was discontinued.
Headache			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 225.0 Milligram Daily Oral

Batch: **Started:** 03/04/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	C-Reactive Protein		16/04/2001	0.62	
	Eosinophils		15/04/2001	0.68	
	Eosinophils		16/04/2001	0.62	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165064 **Seq:** 1
Reported: 01/06/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 62
DOB: 25/05/1939
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium Psychotic disorder			Patient was hsopitalised, clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 06/09/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165065 **Seq:** 1 **Gender:** M
Reported: 01/06/2001 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 28/04/2001 **DOB:** 20/07/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Electrocardiogram abnormal Hyponatraemia Tachycardia			Discontinuation of clozaril and treatment to reverse low sodium counts (unspecified). clozaril was recommenced on 11/5/01.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 01/11/2000 **Stopped:** 28/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Abnormal ecg showed st elevation in antero-lateral leads - 25/05/2001 a consultant cardiologist felt the ecg changes were secondary to different lea d placement.

Additional Information:

The date of onset is not necessarily accuate but indicates onset sometime in the month. the dose start and stop dates are not necessarily accurate but indicates clozaril was started sometime in the month. the patient developed hyponatraemia again when they were not on clozaril. hyponatraemia was due to psychogenic polydipsia.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165189 **Seq:** 1
Reported: 06/06/2001
Hospitalisation: Admitted to hospital
Onset Date: 26/05/2001
Outcome: Unknown

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

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal disorder Dehydration Hypotension		Viral gastro.	Clozaril ceased and the patient was initiated on respiridone.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 15/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patieng had missed his dose of clozaril for 48 hours previous to addmission, and was refusing to take it.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165222 **Seq:** 1 **Gender:** F
Reported: 06/06/2001 **Weight:**
Hospitalisation: **Age:** 68
Onset Date: 23/05/2001 **DOB:** 13/02/1933
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Confusional state		Blood pressure decreased from 145/85 to 85/60.	

Medicine Details:

CLOZARIL (Interaction) **Reason:**
Tablet 12.5 Milligram Daily Oral
Batch: **Started:** 23/05/2001 **Stopped:** CONTIN

TRANYLCYPROMINE SULPHATE (Interaction) **Reason:**
50.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165223 **Seq:** 1
Reported: 06/06/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/05/2001
Outcome: Unknown

Gender: F
Weight:
Age: 17
DOB: 09/12/1983
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Minimal signs of myocarditis.	
Neuroleptic malignant syndrome		Minimal signs of neuroleptic malignant syndrome	Clozaril ceased. patient hospitalised.
Tachycardia		Pulse rate of greater then 135/per minute.	
Pyrexia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 12.5 Milligram Daily Oral

Batch: **Started:** 21/05/2001 **Stopped:** 23/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165224 **Seq:** 1 **Gender:** U
Reported: 06/06/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/05/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
2.0 Gram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165225 **Seq:** 1
Reported: 06/06/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight:
Age: 70
DOB: 04/05/1931
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Diabetes mellitus Hypoaesthesia		Psychosis aggravated	Patient hospitalised. clozaril ceased.

Medicine Details:

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

CLONIDINE HYDROCHLORIDE (Other drug) **Reason:**
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 03/11/1998 **Stopped:** 07/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165305 **Seq:** 1
Reported: 12/06/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unrelated death

Gender: M
Weight:
Age: 30
DOB: 09/12/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Peripheral ischaemia		Lack of circulation in leg	Patient hospitalised

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 06/06/1994 **Stopped:** 21/11/1995

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died in may 2001 by comitting suicide.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165306 **Seq:** 1 **Gender:** M
Reported: 12/06/2001 **Weight:**
Hospitalisation: **Age:** 18
Onset Date: 20/05/2001 **DOB:** 21/02/1983
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Pulse of 104 beats/minute	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	200.0 Milligram	Daily	Oral	
Batch:	**Started:** 26/04/2001		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Normal electrocardiogram.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165307 **Seq:** 1 **Gender:** F
Reported: 12/06/2001 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 05/07/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased Electrocardiogram abnormal Myocarditis			Clozaril ceased.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** 14/05/2001 **Stopped:** 25/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Immunology				Troponin levels raised.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165339 **Seq:** 1 **Gender:** M
Reported: 04/06/2001 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 08/01/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis			Patient was hospitalised and clozaril was discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
0.0
Batch: **Started:** 11/04/1994 **Stopped:** 28/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date is not necessarily accurate but indicates clozaril was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165341 **Seq:** 1 **Gender:** M
Reported: 04/06/2001 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: 01/05/2001 **DOB:** 26/09/1956
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 03/08/1994 **Stopped:** 24/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died in early may 2001.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165342 **Seq:** 1 **Gender:** F
Reported: 06/06/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 25/04/2001 **DOB:** 31/10/1943
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

ASMOL CFC-FREE (Other drug)			**Reason:**	
Inhalation	100.0	Microgram	As necessary	Inhalation
Batch:	**Started:**		**Stopped:**	
ATROVENT (Other drug)			**Reason:**	
Inhalation	20.0	Microgram	As necessary	Inhalation
Batch:	**Started:**		**Stopped:**	
CELEBREX (Other drug)			**Reason:**	
Capsule	200.0	Milligram	As necessary	Oral
Batch:	**Started:**		**Stopped:**	
PANAMAX (Other drug)			**Reason:**	
Tablet	500.0	Milligram	As necessary	Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Post mortem examination gave a cause of death of acute pulmonary oedema caused by congestive cardiac failure. examination of her heart reported 'thin left ventricular muscle' and 'coronaries normal'.

Additional Information:

Patient died 24/4/01. long history of asthma, hypothyroidism and non-insulin dependent diabetes mellitus. patients general medical condition was sufficiently poor to consider it overly conservative to attribute her death to clozapine.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165342 **Seq:** 1 **Gender:** F
Reported: 06/06/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 25/04/2001 **DOB:** 31/10/1943
Outcome: Death **Causality:** Causality possible

Reaction Details:

Medicine Details:

SENEGA AND AMMONIA (Other drug)			**Reason:**	
	10.0	Millilitre	As necessary	
Batch:	**Started:**		**Stopped:**	
BECLOFORTE (Other drug)			**Reason:**	
Inhalation	1.0	Milligram	Daily	Inhalation
Batch:	**Started:**		**Stopped:**	
DIAFORMIN (Other drug)			**Reason:**	
Tablet	2.0	Gram	Daily	Oral
Batch:	**Started:**		**Stopped:**	
DIAMICRON (Other drug)			**Reason:**	
Tablet	160.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	

Laboratory Investigations:

Additional Information:

Patient died 24/4/01. long history of asthma, hypothyroidism and non-insulin dependent diabetes mellitus. patients general medical condition was sufficiently poor to consider it overly conservative to attribute her death to clozapine.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165342 **Seq:** 1 **Gender:** F
Reported: 06/06/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 25/04/2001 **DOB:** 31/10/1943
Outcome: Death **Causality:** Causality possible

Reaction Details:

Medicine Details:

F.G.F. (Other drug)			**Reason:**	
Tablet	1.0	Dose Unspecified	Daily	Oral
Batch:	**Started:**			**Stopped:**
OROXINE (Other drug)			**Reason:**	
Tablet	100.0	Microgram	Daily	Oral
Batch:	**Started:**			**Stopped:**
UREMIDE (Other drug)			**Reason:**	
Tablet	40.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
CLOZARIL (Suspected)			**Reason:**	
Tablet	400.0	Milligram	Daily	Oral
Batch:	**Started:** 18/08/1998			**Stopped:**

Laboratory Investigations:

Additional Information:

Patient died 24/4/01. long history of asthma, hypothyroidism and non-insulin dependent diabetes mellitus. patients general medical condition was sufficiently poor to consider it overly conservative to attribute her death to clozapine.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165632 **Seq:** 1
Reported: 20/06/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/06/2001
Outcome: Recovered

Gender: M
Weight:
Age: 31
DOB: 01/07/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Cardiac failure Chest pain Myocarditis			Admitted to hospital. clozaril was discontinued

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug) **Reason:** Depression
100.0 Milligram Daily
Batch: **Started:** 11/01/2001 **Stopped:**

OLANZAPINE (Other drug) **Reason:** Unspecified psychosis
10.0 Milligram Daily
Batch: **Started:** 04/10/2000 **Stopped:** 22/05/2001

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 16/05/2001 **Stopped:** 04/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				16/5/01: echocardiography showed normal left ventricle size and function; fraction short (39.9%). 4/6/01: echocardiography showed global hypokinesis, mild left ventricular hypertrophy (concentric) and grade 2 ventricle ejection fraction 40-59%. the chest x-ray showed a small pleural effusion. 17/7/01: echocardiography showed mildly dilated left ventricle with normal systolic

Additional Information:

The patient experienced possible myocarditis, chest pains and increased creatine kinase levels, 18 days after commencing clozaril

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165632 **Seq:** 1
Reported: 20/06/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/06/2001
Outcome: Recovered

Gender: M
Weight:
Age: 31
DOB: 01/07/1969
Causality: Causality possible

Reaction Details:

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		**Reason:**	Depression
	100.0 Milligram	Daily	
Batch:	**Started:** 11/01/2001		**Stopped:**
OLANZAPINE (Other drug)		**Reason:**	Unspecified psychosis
	10.0 Milligram	Daily	
Batch:	**Started:** 04/10/2000		**Stopped:** 22/05/2001
CLOZARIL (Suspected)		**Reason:**	Schizophrenia
Tablet	300.0 Milligram	Daily	Oral
Batch:	**Started:** 16/05/2001		**Stopped:** 04/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Function. the aortic root was also mildly dilated. the fraction was short 37.9%. low probability of ventricle perfusion.

Additional Information:

The patient experienced possible myocarditis, chest pains and increased creatine kinase levels, 18 days after commencing clozaril

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165633 **Seq:** 1 **Gender:** U
Reported: 20/06/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165864 **Seq:** 1 **Gender:** M
Reported: 25/06/2001 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 12/02/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Systolic dysfunction.	

Medicine Details:

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

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

ROCALTROL (Other drug) **Reason:**
Tablet 3.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				9th may 2001 he now had moderate global systolic dysfunction with a fractional shortening of 15% and a reduced ejection fraction.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165864 **Seq:** 1 **Gender:** M
Reported: 25/06/2001 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: **DOB:** 12/02/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

ENALAPRIL MALEATE (Other drug)		**Reason:**	
	20.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
CLOZAPINE (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165878 **Seq:** 1
Reported: 27/06/2001
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 100.00
Age: 34
DOB: 04/03/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased Diabetes mellitus		Significant weight gain.	 Required a visit to doctor.

Medicine Details:

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

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

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
275.0 Milligram Daily
Batch: **Started:** 28/03/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				19.1.01 fasting glucose 8.9, hb aic 7%.

Additional Information:

The dose start date for clozapine is not necessarily accurate but indicates the drug was started sometime in the month. sequelae: commencement of oral hypoglycaemics, bsl/dietary monitoring.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165888 **Seq:** 1 **Gender:** F
Reported: 27/06/2001 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 31/05/2001 **DOB:** 18/10/1952
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female	Life threatening	Breast cancer.	Reaction was life threatening.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
425.0 Milligram Daily
Batch: **Started:** 31/12/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset for clozaril is not accurate but indicates onset sometime in the year. recently diagnosed with breast cancer with probable secondary spread to lungs, bone and liver.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165898 **Seq:** 1 **Gender:** M
Reported: 27/06/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 06/08/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Clozaril withdrawn. treated with lisinopril and digoxin.

Medicine Details:

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

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

DIAZEPAM (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 21/05/2001 **Stopped:** 20/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Echocardiogram showed mild cardiomyopathy: ejection fraction (ef): 49% - 52%.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165905 **Seq:** 1 **Gender:** U
Reported: 28/06/2001 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Fatigue		Mild sedation.	
Myalgia		Non-specific aches and pains in legs and body.	
Dyspnoea			
Myocarditis			
Salivary hypersecretion			
Tachycardia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 01/06/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				An ecg showed marked st depression and t-wave inversion in the lateral and inferior leads. an echocardiogram showed a hyperdynamic beat with a left ventricular size at the upper limit of normal. measures taken included discontinuation of clozaril. the patient was re-challenged 2 years later with a dose of 225mg.

Additional Information:

The dose start for clozaril is not necessarily accurate but indicates that the drug was started sometime in june 1994. 165297 is a duplicate of 165905.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 165905 **Seq:** 1 **Gender:** U
Reported: 28/06/2001 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	200.0 Milligram	Daily	Oral

Batch: **Started:** 01/06/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Prior to re-challenge and ecg still showed evidence of t-wave flattening and st depression, but echochardiography showed only insignificant mitral regurgitation. the ecg findings remain unchanged during the re-challenge.

Additional Information:

The dose start for clozaril is not necessarily accurate but indicates that the drug was started sometime in june 1994. 165297 is a duplicate of 165905.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166333 **Seq:** 1
Reported: 11/07/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 30
DOB: 24/04/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia Hypotension Pyrexia Syncope			Admitted to hospital and resusscitated with iv fluids and adrenaline.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 475.0 Milligram Daily Oral

Batch: **Started:** 01/03/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for clozaril is not necessarily accurate but indicates that clozaril was started sometime in march 2001.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166334 **Seq:** 1 **Gender:** F
Reported: 11/07/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypercalcaemia	Severe	Severe.	Clozaril ceased temporarily. given granulocyte colony-stimulating factor.
Hyperphosphataemia	Severe	Severe.	
Agranulocytosis			
Neutropenia			
Pseudolymphoma			
Pyrexia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 0.0 Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Bone marrow biopsy which showed agranulocytosis and mild myeloblastic changes attributed to an acute drug effect. bone marrow aspirate revealed a diffuse large b-cell lymphoma.

Additional Information:

Relevant medical history - treatment-resistant schizophrenia. journal: british journal of psychiatry author: hundertmark,j., campbell,p. title: reintroduction of clozapine after diagnosis of lymphoma. volume: 178, year:2001, page 576.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166336 **Seq:** 1 **Gender:** M
Reported: 11/07/2001 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: **DOB:** 03/12/1950
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lymphocytic leukaemia Lymphoma Fatigue		Chronic lymphocytic leukaemia. Low-grade lymphoma.	Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 08/06/2001 **Stopped:** 28/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology		08/06/2001	7.5X10.9/L	
	Haematology		22/06/2001	7.1X10.9/L	
	Histology				Chronic lymphocytic leukaemia, low-grade lymphoma and tiredness.
	White blood cells		08/06/2001	16X10.9/L	
	White blood cells		22/06/2001	17.2X10.9L	

Additional Information:

The dose stop date for the drug clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166372 **Seq:** 1
Reported: 12/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/07/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 58Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Blood creatine phosphokinase incr Neuroleptic malignant syndrome		Altered conscious state	Supportive treatment in intensive care unit. cessation of clozapine.

Medicine Details:

VENTOLIN (Other drug) **Reason:**
100.0 Microgram As necessary
Batch: **Started:** **Stopped:**

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

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

QVAR AUTOHALER (Other drug) **Reason:**
Inhalation 400.0 Microgram Daily Inhalation
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck 5/7/01 >5000

Additional Information:

Brought to emergency department in altered conscious state. blood pressure and temperature dysregulation.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166372 **Seq:** 1
Reported: 12/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/07/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 58Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

MULTI-B FORTE (Other drug)		**Reason:**	
	1.0 Dose Unspecified	Daily	
Batch:	**Started:**		**Stopped:**
FOLINIC ACID (Other drug)		**Reason:**	
	5.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
CLOZAPINE (Suspected)		**Reason:**	
	450.0 Milligram	Daily	
Batch:	**Started:** 17/07/1998		**Stopped:** 04/07/2001

Laboratory Investigations:

Additional Information:

Brought to emergency department in altered conscious state. blood pressure and temperature dysregulation.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166421 **Seq:** 1 **Gender:** M
Reported: 11/07/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 29/06/2001 **DOB:** 06/02/1972
Outcome: Unrelated death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Patient died by hanging.	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 01/06/2001 **Stopped:** 29/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166462 **Seq:** 1 **Gender:** M
Reported: 16/07/2001 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 28/06/2001 **DOB:** 14/02/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Renal impairment			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/02/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for clozaril is also no accurate but indicated the drug was commenced sometime in the month indicated.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166501 **Seq:** 1
Reported: 17/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 11/03/2001
Outcome: Recovered with sequelae

Gender: M
Weight:
Age: 27
DOB: 21/02/1974
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism			Patient required icu admission due to difficulties in management. reaction treated with shunt.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Schizophrenia
400.0 Milligram Daily
Batch: **Started:** 15/02/2000 **Stopped:** 15/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166701 **Seq:** 1
Reported: 23/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/07/2001
Outcome: Recovered

Gender: M
Weight:
Age: 50
DOB: 05/09/1950
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Miosis		Pupils were pinpoint and non reactive	
Coma			
Dysphagia			
Faecal incontinence			
Myocardial infarction			
Respiratory depression			
Salivary hypersecretion			Hospitalised
Urinary incontinence			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 07/07/1995 **Stopped:** 06/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient suffered a cerebrovascular accident one month ago and when taking clozaril previously in 1995 also experienced a cva.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166802 **Seq:** 1
Reported: 24/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 12/01/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 34
DOB: 10/10/1966
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ketosis		Diabetic ketoacidosis	Patient was admitted to hospital, treated with insulin infusion, clozapine ceased, quetiapine and insulin treatment commenced.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166842 **Seq:** 1 **Gender:** M
Reported: 25/07/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 05/07/2001 **DOB:** 24/07/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis		Greatly increased white blood cell & neutrophil ct	.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 325.0 Milligram Daily Oral

Batch: **Started:** 22/12/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		17/12/1998	6.3	
	Neutrophils		05/07/2001	19.2	
	White blood cells		17/12/1998	11.4	
	White blood cells		05/07/2001	21.6	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166843 **Seq:** 1 **Gender:** F
Reported: 25/07/2001 **Weight:**
Hospitalisation: **Age:** 18
Onset Date: 01/07/2001 **DOB:** 03/08/1982
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral			Clozaril reduced to 300 mg daily.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 15/06/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Intermittent falls (20 seconds to one minute) with no loss of consciousness. she also had diminished power and sensation progressing from legs to also involve the uppr limbs. onset date is not necessarily accurate but indicates onset sometime in the month. dose start date for the drug clozaril is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166844 **Seq:** 1
Reported: 25/07/2001
Hospitalisation: Hospitalisation prolonged
Onset Date: 01/07/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 58
DOB: 15/11/1942
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood pressure fluctuation			
Confusional state			
Consciousness fluctuating			
Hallucination			
Neuroleptic malignant syndrome			Clozaril discontinued. admitted to hospital. supportive therapy in inten- sive care unit.
Pyrexia			
Somnolence			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 450.0 Milligram Daily Oral

Batch: **Started:** 24/07/1998 **Stopped:** 04/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166846 **Seq:** 1
Reported: 25/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/07/2001
Outcome: Recovered

Gender: M
Weight:
Age: 37
DOB: 30/08/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Unconscious for 20 minutes.	Patient hospitalised. given epilim 500mg twice daily increasing to 1gm twice daily. patient also given seroquel.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 700.0 Milligram Daily Oral

Batch: **Started:** 16/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Electroencephalogram consistent with epilepsy.

Additional Information:

The onset date is not necessarily accurate but indicates onset sometime in the month. the dose of clozarily was reduced fdrom 700mg to 600mg and finally to 500mg daily.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166908 **Seq:** 1
Reported: 27/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/07/2001
Outcome: Recovered

Gender: M
Weight: 55.00
Age: 20
DOB: 20/09/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			
Leukopenia	Life threatening		Clozaril creased and lenograstin 263mg sc daily. reactions were life threatening. patient was hospitalised.
Neutropenia	Life threatening		

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
175.0 Milligram Daily
Batch: **Started:** 18/06/2001 **Stopped:** 17/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		07/06/2001	2.04	
	Neutrophils		25/07/2001	1.93	
	Neutrophils		18/07/2001	1.56	
	Neutrophils		17/07/2001	1.36	
	Neutrophils		24/07/2001	0.25	
	Neutrophils		21/07/2001	0.44	
	Neutrophils		23/07/2001	0.56	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166908 **Seq:** 1
Reported: 27/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/07/2001
Outcome: Recovered

Gender: M
Weight: 55.00
Age: 20
DOB: 20/09/1980
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
175.0 Milligram Daily
Batch: **Started:** 18/06/2001 **Stopped:** 17/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/07/2001	0.44	
	Neutrophils		20/07/2001	0.31	
	Neutrophils		19/07/2001	0.90	
	White blood cells		07/06/2001	4.6	
	White blood cells		25/07/2001	4.2	
	White blood cells		17/07/2001	2.8	
	White blood cells		18/07/2001	3.1	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166908 **Seq:** 1
Reported: 27/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/07/2001
Outcome: Recovered

Gender: M
Weight: 55.00
Age: 20
DOB: 20/09/1980
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
175.0 Milligram Daily
Batch: **Started:** 18/06/2001 **Stopped:** 17/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		19/07/2001	2.3	
	White blood cells		24/07/2001	1.9	
	White blood cells		20/07/2001	1.4	
	White blood cells		21/07/2001	1.7	
	White blood cells		22/07/2001	1.5	
	White blood cells		23/07/2001	1.5	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166917 **Seq:** 1
Reported: 27/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/07/2001
Outcome: Unknown

Gender: M
Weight:
Age: 30
DOB: 13/08/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Pneumonia			Clozapine ceased 12/07/2001. admitted to hospital. given roxithromycin.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
0.0
Batch: **Started:** 23/04/2001 **Stopped:** 12/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		23/04/2001	4.5	
	Neutrophils		21/05/2001	4.3	
	Neutrophils		18/06/2001	3.5	
	Neutrophils		12/07/2001	6.4	
	Neutrophils		06/07/2001	1.3	
	White blood cells		23/04/2001	8.2	Fbe date 12/07/2001: hb 160, wcc 8.4, plt 265, neuts 6.4
	White blood cells		21/05/2001	7.0	Fbe date 12/07/2001: hb 160, wcc 8.4, plt 265, neuts 6.4

Additional Information:

On 06/07/2001 the patient's neutrophil count was 1.3 x 10 9/l and the patient's clozapine was ceased on 12/07/2001. patient also taking - roxithromycin, prednisolone, haloperidol and clonazepam.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166917 **Seq:** 1
Reported: 27/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/07/2001
Outcome: Unknown

Gender: M
Weight:
Age: 30
DOB: 13/08/1970
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
0.0
Batch: **Started:** 23/04/2001 **Stopped:** 12/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		18/06/2001	7.0	Fbe date 12/07/2001: hb 160, wcc 8.4, plt 265, neuts 6.4
	White blood cells		06/07/2001	3.7	Fbe date 12/07/2001: hb 160, wcc 8.4, plt 265, neuts 6.4
	White blood cells		12/07/2001	8.4	Fbe date 12/07/2001: hb 160, wcc 8.4, plt 265, neuts 6.4

Additional Information:

On 06/07/2001 the patient's neutrophil count was 1.3 x 10 9/l and the patient's clozapine was ceased on 12/07/2001. patient also taking - roxithromycin, prednisolone, haloperidol and clonazepam.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 166918 **Seq:** 1 **Gender:** M
Reported: 27/07/2001 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 12/07/2001 **DOB:** 05/03/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutrophil count decreased.	Clozapine ceased.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
50.0 Milligram Daily
Batch: **Started:** 25/06/2001 **Stopped:** 12/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		28/06/2001	1.7	
	Neutrophils		02/07/2001	2.2	
	Neutrophils		14/07/2001	1.8	
	Neutrophils		12/07/2001	1.0	
	White blood cells		28/06/2001	3.7	
	White blood cells		02/07/2001	4.5	
	White blood cells		12/07/2001	3.2	

Additional Information:

Patient also taking - valproate sodium, haloperidol, benztropine mesylate and diazepam. clozapine was increased from 50mg to 100mg on 02/07/2001 and 150mg on 09/07/2001.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167165 **Seq:** 1 **Gender:** F
Reported: 28/05/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 03/04/2001 **DOB:** 27/09/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia			Propranolol given.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 28/03/2001 **Stopped:** 17/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167178 **Seq:** 1 **Gender:** M
Reported: 03/08/2001 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 21/06/2001 **DOB:** 16/03/1971
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 01/04/2000 **Stopped:** 21/06/2001

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

CLONIDINE HYDROCHLORIDE (Suspected) **Reason:**
300.0 Microgram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had also been taking other illicit drugs.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167178 **Seq:** 1 **Gender:** M
Reported: 03/08/2001 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 21/06/2001 **DOB:** 16/03/1971
Outcome: Death **Causality:** Causality possible

Reaction Details:

Medicine Details:

RANITIDINE (Suspected) **Reason:**
150.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Additional Information:

Patient had also been taking other illicit drugs.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167187 **Seq:** 1
Reported: 03/08/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 31
DOB: 17/11/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Aphasia		Non coherent, psychotic symptoms	Patient had to be hospitalised

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 27/02/1997 **Stopped:** 11/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167213 **Seq:** 1 **Gender:** M
Reported: 06/08/2001 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 31/12/1996 **DOB:** 11/01/1943
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia			Ceased clozaril.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 07/05/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate bu indicates that onset sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167238 **Seq:** 1 **Gender:** F
Reported: 06/08/2001 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 24/07/2001 **DOB:** 29/04/1953
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis		Neutrophil count decreased.	

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 17/04/2001 **Stopped:** 23/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		23/07/2001	1.4	
	Neutrophils		24/07/2001	2.3	
	White blood cells		23/07/2001	3.5	
	White blood cells		24/07/2001	4.7	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167252 **Seq:** 1 **Gender:** M
Reported: 19/04/2001 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 07/09/2000 **DOB:** 04/03/1969
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 25/11/1996 **Stopped:** 07/09/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		07/09/2000	1.4	Pre-treatment 25.11.1996 - nc 4.1.
	Neutrophils		08/09/2000	1.6	Pre-treatment 25.11.1996 - nc 4.1.
	White blood cells		07/09/2000	3.4	Pre-treatment 25.11.1996 - wbc 7.2.
	White blood cells		08/09/2000	3.4	Pre-treatment 25.11.1996 - wbc 7.2.

Additional Information:

Past history of neutropenia with thioridazine (about 10 years ago), not documented and not known until recently.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167253 **Seq:** 1 **Gender:** M
Reported: 23/05/2001 **Weight:**
Hospitalisation: **Age:** 46
Onset Date: 02/03/2001 **DOB:** 08/01/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly Eosinophilia		Left ventricular hypertrophy.	 Clozaril ceased on 12.3.01.

Medicine Details:

CLOZARIL (Suspected)		**Reason:**		
Tablet	400.0 Milligram	Daily	Oral	
Batch:	**Started:** 26/11/2000		**Stopped:**	CONTIN
WARFARIN SODIUM (Suspected)		**Reason:**		
	7.0 Milligram	Daily		
Batch:	**Started:** 26/11/2000		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Echocardiogram performed on 2.3.01 revealed left ventricular hypertrophy (clinically asymptomatic).

Additional Information:

Eosinophil count was noted to be rising since the patient commenced clozaril.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167254 **Seq:** 1 **Gender:** M
Reported: 12/06/2001 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 28/03/2001 **DOB:** 23/07/1962
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia Leukopenia Neutropenia Thrombocytopenia			Clozaril ceased.

Medicine Details:

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

SODIUM VALPROATE (Other drug) **Reason:**
3.0 Gram Daily
Batch: **Started:** **Stopped:**

CLONAZEPAM (Other drug) **Reason:**
0.5 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 31/01/2001 **Stopped:** 27/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167255 **Seq:** 1 **Gender:** M
Reported: 19/04/2001 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: 05/01/2001 **DOB:** 30/06/1957
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 20/12/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167256 **Seq:** 1 **Gender:** F
Reported: 28/06/2001 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 28/04/2001 **DOB:** 23/02/1977
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Low grade pyrexia.	
Tachycardia		Pulse rate of 130.	Temporary discontinuation of clozaril.
Urinary tract infection			
Vomiting			

Medicine Details:

OLANZAPINE (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** **Stopped:** 05/04/2001

PARACETAMOL (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:**

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 275.0 Milligram Daily Oral
Batch: **Started:** 02/04/2001 **Stopped:** 15/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167259 **Seq:** 1 **Gender:** F
Reported: 12/06/2001 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 10/05/2001 **DOB:** 25/07/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 575.0 Milligram Daily Oral

Batch: **Started:** 14/03/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167260 **Seq:** 1 **Gender:** M
Reported: 04/07/2001 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 16/05/2001 **DOB:** 01/05/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia Convulsion Syncope Thinking abnormal			Discontinuation of concomitant zyban.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 28/03/2000 **Stopped:** CONTIN

ZYBAN SR (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This patient experienced minor seizures, blackouts, extreme memory loss, impaired congnitive function after commencing clozaril.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167284 **Seq:** 1
Reported: 11/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/05/2001
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 53
DOB: 29/08/1947
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Leukaemia Neutropenia			Clozaril ceased. admitted to hospital. given granulocyte stimulating factor.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** 01/01/1994 L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		14/06/1994	5.8X10 9/L	
	Neutrophils		24/04/2001	0.8X10 9/L	
	Neutrophils		25/04/2001	0.6X10 9/L	
	Neutrophils		01/05/2001	0.47X109/L	
	Neutrophils		30/04/2001	0.5X10 9/L	
	Neutrophils		26/04/2001	0.6X10 9/L	
	White blood cells		14/06/1994	8.5X10 9/L	

Additional Information:

Patient has been receiving clozaril continuously for approximately 7 years. patient experienced agranulocytosis on the 15/06/2001.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167284 **Seq:** 1
Reported: 11/05/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/05/2001
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 53
DOB: 29/08/1947
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** 01/01/1994 L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		24/04/2001	2.3X10 9/L	
	White blood cells		25/04/2001	2.3X10 9/L	
	White blood cells		26/04/2001	2.3X10 9/L	
	White blood cells		30/04/2001	2.3X10 9/L	
	White blood cells		01/05/2001	3.4X10 9/L	

Additional Information:

Patient has been receiving clozaril continuously for approximately 7 years. patient experienced agranulocytosis on the 15/06/2001.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167340 **Seq:** 1 **Gender:** M
Reported: 08/08/2001 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: 11/04/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia	Required Specialist Consultation		Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 21/03/2001 **Stopped:** 11/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167371 **Seq:** 1 **Gender:** M
Reported: 09/08/2001 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: 31/12/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 01/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year. the dose start date is not accurate but indicates the drug was started sometim e in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167372 **Seq:** 1 **Gender:** M
Reported: 09/08/2001 **Weight:**
Hospitalisation: **Age:** 18
Onset Date: **DOB:** 01/06/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Neuroleptic malignant syndrome			Clozaril ceased. reaction treated with quetiapine and heparin

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 16/07/2001 **Stopped:** 28/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167377 **Seq:** 1
Reported: 09/08/2001
Hospitalisation: Admitted to hospital
Onset Date: 30/07/2001
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 49
DOB: 30/08/1951
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depression Suicide attempt			Hospitalised, electroconvulsive therapy. discharged to rehabilitation centre to continue the therapy course.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	350.0 Milligram	Daily	Oral
Batch:	**Started:** 30/03/2001	**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167378 **Seq:** 1
Reported: 09/08/2001
Hospitalisation: Admitted to hospital
Onset Date: 07/08/2001
Outcome: Recovered

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

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Influenza like illness Myocarditis Pericarditis Pleuritic pain Pyrexia			Patient hospitalised. treated with high dose methylprednisolone, ace inhibitor and beta blockers.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia

0.0

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine				Ck = 170
	Other data				Myopericarditis with impaired lv ejection fraction on echo. 3/7/01 - 2d, doppler and colour flow mapping: left ventricle: normal size, moderate impairment systolic function, (global), estimated ejections fraction: (35 -40%), no thrombos. right ventricle: normal size, impaired functio
	Troponin				Troponin 3.47

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167417 **Seq:** 1
Reported: 13/08/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 105.00
Age: 43
DOB: 25/01/1958
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation Leukopenia			Patient hospitalised. clozapine ceased. date of recovery 01/08/2001. required disimpaction - 1 admission (25 - 27/07/2001). clozapine ceased.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
375.0 Milligram Daily
Batch: **Started:** 05/04/1999 **Stopped:** 22/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167449 **Seq:** 1 **Gender:** M
Reported: 09/08/2001 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 24/07/2001 **DOB:** 18/12/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia Leukocytosis			Clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 375.0 Milligram Daily Oral

Batch: **Started:** 11/07/2001 **Stopped:** 25/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils		24/07/2001	5.8	
	Eosinophils		25/07/2001	7.8	
	Neutrophils		24/07/2001	9.10	
	Neutrophils		25/07/2001	9.6	
	White blood cells		24/07/2001	18.6	
	White blood cells		25/07/2001	21.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167485 **Seq:** 1
Reported: 23/05/2001
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 39
DOB: 19/04/1962
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness Syncope			Prolonged hospitalisation. clozaril was reduced.

Medicine Details:

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

KEFLEX (Other drug) **Reason:** Influenza,unqualified
0.0
Batch: **Started:** **Stopped:**

DICLOCIL (Other drug) **Reason:** Influenza,unqualified
0.0
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has a normal echo.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167485 **Seq:** 1
Reported: 23/05/2001
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 39
DOB: 19/04/1962
Causality: Causality possible

Reaction Details:

Medicine Details:

ALCOHOL (Suspected)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	500.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/08/2000		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

The patient has a normal echo.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167517 **Seq:** 1 **Gender:** M
Reported: 03/08/2001 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 28/02/2001 **DOB:** 26/08/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

BENZTROPINE MESYLATE (Suspected) **Reason:**
0.5 Milligram Daily
Batch: **Started:** **Stopped:**

SODIUM VALPROATE (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** **Stopped:**

HALOPERIDOL (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167592 **Seq:** 1 **Gender:** M
Reported: 16/08/2001 **Weight:** 68.00
Hospitalisation: **Age:** 27Y
Onset Date: 11/06/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Thrombocytopenia			

Medicine Details:

LUVOX (Other drug) **Reason:** Depression
50.0 Milligram Daily
Batch: **Started:** 01/04/2001 **Stopped:** CONTIN

EPILIM (Suspected) **Reason:**
Oral application 1.4 Gram Daily Oral
Batch: **Started:** 01/01/1999 **Stopped:** 15/06/2001

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
500.0 Milligram Daily
Batch: **Started:** 01/04/2001 **Stopped:** 15/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		11/06/2001	1.65	
	Neutrophils		15/06/2001	1.39	
	White blood cells		11/06/2001	3.5	
	White blood cells		15/06/2001	3.0	

Additional Information:

The dose start date for clozaril and luvox is not accurate but indicates the d rugs were started sometime in the month

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167639 **Seq:** 1
Reported: 16/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 05/06/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 29
DOB: 08/10/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 16/02/1999 **Stopped:** 05/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		28/06/2001	2.0	
	Neutrophils		22/06/2001	1.1	
	Neutrophils		12/06/2001	1.80	
	Neutrophils		05/06/2001	1.1	
	Neutrophils		07/06/2001	2.6	
	White blood cells		28/06/2001	4.2	
	White blood cells		22/06/2001	3.0	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167639 **Seq:** 1
Reported: 16/07/2001
Hospitalisation: Admitted to hospital
Onset Date: 05/06/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 29
DOB: 08/10/1971
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 16/02/1999 **Stopped:** 05/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		12/06/2001	2.90	
	White blood cells		07/06/2001	4.30	
	White blood cells		05/06/2001	2.2	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167641 **Seq:** 1 **Gender:** F
Reported: 23/07/2001 **Weight:**
Hospitalisation: **Age:** 75
Onset Date: 20/06/2001 **DOB:** 27/02/1926
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia Somnolence		Bronchopneumonia.	Treated with augmentin, rulide and cephalexin.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 18/06/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167647 **Seq:** 1 **Gender:** M
Reported: 15/08/2001 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 01/08/2001 **DOB:** 23/10/1980
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 3.1 Gram Total Oral
Batch: **Started:** 26/02/2001 **Stopped:** 01/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				3.8.01: clozapine blood level - 1737 and norclozapine - 805.

Additional Information:

Patient had previously taken clozaril from 29.9.00 to 11.1.01.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167662 **Seq:** 1 **Gender:** F
Reported: 06/08/2001 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: 18/07/2001 **DOB:** 10/05/1978
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Fine white rash on arms.	
Pyrexia		High fever.	
Blood creatine phosphokinase incr			
Leukopenia			
Neutropenia			
Pharyngitis			
Tachycardia			
Troponin increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 06/07/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine kinase MB		17/07/2001	9U/L	
	Creatine kinase MB		19/07/2001	22U/L	
	Creatine kinase MB		23/07/2001	-	
	Creatine phosphokinase	<161	17/07/2001	545U/L	
	Creatine phosphokinase	<161	19/07/2001	366	
	Creatine phosphokinase	<161	23/07/2001	57U/L	
	Troponin				Troponin level of 3.3.

Additional Information:

Patient also had upper respiratory tract infection at the same time as the fever.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167722 **Seq:** 1 **Gender:** M
Reported: 24/08/2001 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: 01/08/2001 **DOB:** 28/04/1957
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 25/05/2001 **Stopped:** 01/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167729 **Seq:** 1 **Gender:** F
Reported: 20/08/2001 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 10/08/2001 **DOB:** 01/08/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** 13/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		10/08/2001	1.1	
	White blood cells		10/08/2001	237	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167732 **Seq:** 1
Reported: 20/08/2001
Hospitalisation: Admitted to hospital
Onset Date: 04/07/2001
Outcome: Recovered

Gender: M
Weight:
Age: 24
DOB: 27/09/1976
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Enteritis Leukocytosis		Acute appendicitis.	Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 225.0 Milligram Daily Oral

Batch: **Started:** 19/12/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		19/12/2000	3.9	
	Neutrophils		04/07/2001	18.8	
	Neutrophils		07/08/2001	3.3	
	White blood cells		19/12/2000	6.2	
	White blood cells		04/07/2001	21.9	
	White blood cells		07/08/2001	6.3	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167775 **Seq:** 1
Reported: 22/08/2001
Hospitalisation: Admitted to hospital
Onset Date: 25/07/2001
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 22
DOB: 24/12/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Pneumonia Pyrexia Respiratory disorder Tachycardia			Patient hospitalised.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
350.0 Milligram Daily
Batch: **Started:** 01/05/2001 **Stopped:** 04/08/2001

HALOPERIDOL (Suspected) **Reason:** Unspecified psychosis
5.0 Milligram Daily
Batch: **Started:** 11/07/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Echo (cardiac) - showed 30% ejection fraction and signs of cardiomyopathy. on 31/07/01 patient developed right lower lobe consolidation tachypnoea, tachycardia and fever.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167796 **Seq:** 1
Reported: 23/08/2001
Hospitalisation:
Onset Date: 08/06/2001
Outcome: Not yet recovered

Gender: M
Weight: 80.00
Age: 21
DOB: 04/03/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspepsia Chest pain Vomiting		Gastric reflux.	 Given acimax. required a visit to doctor.

Medicine Details:

VENTOLIN (Other drug) **Reason:** Other diseases of esophagus

Inhalation	4.0	Dose Unspecified	Daily	Inhalation

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

CLOPINE (Suspected) **Reason:**

Oral Liquid	400.0	Milligram	Daily	Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of nausea and vomiting - on prozac.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167813 **Seq:** 1
Reported: 23/08/2001
Hospitalisation: Admitted to hospital
Onset Date: 31/07/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 22Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure	Severe	Severe.	
Cardiomyopathy	Severe	Severe.	
Dyspnoea	Severe	Severe.	
Pneumonia	Severe	Severe.	Patient hospitalised. clozapine ceased. treated with roxithromycin and beta blockers.
Pyrexia	Severe	Severe.	

Medicine Details:

CLOPINE (Suspected) **Reason:**

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 5D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Routine echocardiogram taken just prior to the episode of pneumonia showed cardiomyopathy. cardia echo showed 30% ejection fraction.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167814 **Seq:** 1
Reported: 23/08/2001
Hospitalisation: Admitted to hospital
Onset Date: 16/08/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 47
DOB: 25/03/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Severe	Severe.	
Fatigue	Severe	Severe.	
Hypotension	Severe	Severe.	
Myocarditis	Severe	Severe.	Patient hospitalised. clozapine ceased.
Nausea	Severe	Severe.	
Tachycardia	Severe	Severe.	
Troponin increased	Severe	Severe.	
Vomiting	Severe	Severe.	

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
Tablet 1.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

THYROXINE SODIUM (Other drug) **Reason:**
Tablet 100.0 Microgram Daily Oral
Batch: **Started:** **Stopped:**

RANITIDINE (Other drug) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 31/07/2001 **Stopped:** 20/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin		20/08/2001	0.58	Breathlessness on lying.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167820 **Seq:** 1
Reported: 23/08/2001
Hospitalisation: Admitted to hospital
Onset Date: 13/02/2001
Outcome: Unknown

Gender: M
Weight:
Age: 40
DOB: 28/04/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Exacerbation of mental illness.	Admitted to hospital. clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 28/11/2000 **Stopped:** 13/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167849 **Seq:** 1
Reported: 24/08/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 27
DOB: 29/11/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Neutropenia Pyrexia			Patient hospitalised. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 08/05/2001 **Stopped:** 11/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		26/04/2001	3.5	
	Neutrophils		12/08/2001	1.1	
	Neutrophils		14/08/2001	2.3	
	Neutrophils		13/08/2001	1.7	
	White blood cells		26/04/2001	6.2	
	White blood cells		12/08/2001	3.3	
	White blood cells		13/08/2001	4.4	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167849 **Seq:** 1
Reported: 24/08/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 27
DOB: 29/11/1973
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	300.0 Milligram	Daily	Oral
Batch:	**Started:** 08/05/2001	**Stopped:**	11/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		14/08/2001	4.7	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167851 **Seq:** 1
Reported: 24/08/2001
Hospitalisation: Treated in outpatient department only.
Onset Date: 28/07/2001
Outcome: Unknown

Gender: M
Weight:
Age: 26
DOB: 26/03/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Cardiomyopathy Myocarditis			Treated with an ace inhibitor.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 550.0 Milligram Daily Oral

Batch: **Started:** 22/12/1999 **Stopped:** 02/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167852 **Seq:** 1 **Gender:** M
Reported: 24/08/2001 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 06/08/2001 **DOB:** 01/04/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Clozaril ceased

Medicine Details:

EPILIM (Other drug) **Reason:** Other&unspecified epilepsy
2.5 Gram Daily
Batch: **Started:** **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 22/06/1998 **Stopped:** 06/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/06/1998	4.0	
	Neutrophils		06/08/2001	1.42	
	Neutrophils		10/08/2001	1.53	
	Neutrophils		17/08/2001	6.57	
	Neutrophils		13/08/2001	1.80	
	White blood cells		22/06/1998	6.8	
	White blood cells		06/08/2001	5.84	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167852 **Seq:** 1 **Gender:** M
Reported: 24/08/2001 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 06/08/2001 **DOB:** 01/04/1967
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

EPILIM (Other drug) **Reason:** Other&unspecified epilepsy
2.5 Gram Daily
Batch: **Started:** **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 22/06/1998 **Stopped:** 06/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		10/08/2001	5.88	
	White blood cells		13/08/2001	6.24	
	White blood cells		17/08/2001	6.57	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167864 **Seq:** 1 **Gender:** F
Reported: 27/08/2001 **Weight:** 94.00
Hospitalisation: **Age:** 45Y
Onset Date: 15/07/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Blood creatine phosphokinase incr Left ventricular failure Nausea Troponin increased Vomiting		Exertional dyspnoea.	None.

Medicine Details:

THYROXINE SODIUM (Other drug)			**Reason:**		
Tablet	100.0	Microgram	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		
BENZTROPINE MESYLATE (Other drug)			**Reason:**		
Tablet	2.0	Milligram	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		
RANITIDINE (Other drug)			**Reason:**		
Tablet	150.0	Milligram	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		
COLOXYL (Other drug)			**Reason:**		
Oral application	6.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**	L TERM	**Stopped:**		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				New onset mild lv dysfunction on cardiac echo.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 167864 **Seq:** 1
Reported: 27/08/2001
Hospitalisation:
Onset Date: 15/07/2001
Outcome: Not yet recovered

Gender: F
Weight: 94.00
Age: 45Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)				**Reason:**	Unspecified schizophrenia
Tablet	175.0	Milligram	Daily		Oral
Batch:	**Started:**			**Stopped:**	20/08/2001

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168102 **Seq:** 1 **Gender:** M
Reported: 03/09/2001 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 10/10/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension			Nifedipine 20mg.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** 16/05/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168103 **Seq:** 1
Reported: 03/09/2001
Hospitalisation: Admitted to hospital
Onset Date: 02/07/2001
Outcome: Recovered

Gender: M
Weight:
Age: 24
DOB: 24/06/1977
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Myocarditis Troponin increased			Patient was admitted to hospital for an electrocardiogram and echocardiogram, a biopsy and treatment (not specified). ceased clozaril. treated with panadol and valium.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 275.0 Milligram Daily Oral

Batch: **Started:** 19/06/2001 **Stopped:** 02/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine kinase MB		02/07/2001	253	
	Troponin	BASELINE 0.05	02/07/2001	0.48	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168105 **Seq:** 1 **Gender:** M
Reported: 03/09/2001 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 28/06/2001 **DOB:** 12/10/1950
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Tachycardia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 450.0 Milligram Daily Oral

Batch: **Started:** 01/06/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has experienced symptoms since commencing clozaril in approximately june 2001. measures taken included reducing the dose of clozaril to 500mg daily. symptoms subsided for a short time then reaction continues, the doctor indicates that clozaril may be reduced. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily acurate but indicates clozaril was started sometime in the month

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168143 **Seq:** 1
Reported: 05/09/2001
Hospitalisation: Admitted to hospital
Onset Date: 10/08/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 15/01/1961
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Raised creatine kinase levels.	
Confusional state			
Neuroleptic malignant syndrome			Admitted to hospital

Medicine Details:

CLONIDINE HYDROCHLORIDE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** 27/07/2001

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 16/02/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		13/08/2001	860	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168197 **Seq:** 1 **Gender:** M
Reported: 09/08/2001 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 06/06/2001 **DOB:** 22/01/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 02/06/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril treatment was abandoned due to the patient's non-compliance and he had to be hospitalised because of his schizophrenia symptoms.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168266 **Seq:** 1 **Gender:** M
Reported: 10/09/2001 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: **DOB:** 20/05/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		No ejaculatory fluid.	Dose reduction of clozaril.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 07/08/2000 **Stopped:** 05/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168314 **Seq:** 1 **Gender:** M
Reported: 10/09/2001 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 28/08/2001 **DOB:** 15/12/1952
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Leukocytosis Renal failure acute Syncope			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 08/08/2001 **Stopped:** 28/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		15/08/2001	12.3	
	Radiololgy				Ultrasound showed an enlarged heart and liver.
	White blood cells		15/08/2001	16.2	

Additional Information:

The dose stop date is not necessarily accurate but indicates the drug was stopped sometime in the month. the date of onset is not necessarily accurate but indicates onset sometime in the month. patient was found to have septicaemia and bilateral pneumonia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168332 **Seq:** 1 **Gender:** F
Reported: 20/08/2001 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: 28/06/2001 **DOB:** 07/06/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 325.0 Milligram Daily Oral

Batch: **Started:** 08/05/2001 **Stopped:** 28/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		01/05/2001	3.3	
	Neutrophils		28/06/2001	1.3	
	Neutrophils		01/07/2001	2.8	
	Neutrophils		30/06/2001	1.8	
	Neutrophils		12/07/2001	4.6	
	Neutrophils		26/07/2001	6.8	
	Neutrophils		19/07/2001	4.7	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168332 **Seq:** 1 **Gender:** F
Reported: 20/08/2001 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: 28/06/2001 **DOB:** 07/06/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 325.0 Milligram Daily Oral

Batch: **Started:** 08/05/2001 **Stopped:** 28/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		05/07/2001	3.1	
	Neutrophils		03/07/2001	2.8	
	White blood cells		01/05/2001	5.1	
	White blood cells		28/06/2001	3.2	
	White blood cells		30/06/2001	5.1	
	White blood cells		01/07/2001	5.3	
	White blood cells		03/07/2001	5.0	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168332 **Seq:** 1 **Gender:** F
Reported: 20/08/2001 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: 28/06/2001 **DOB:** 07/06/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 325.0 Milligram Daily Oral

Batch: **Started:** 08/05/2001 **Stopped:** 28/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		05/07/2001	5.3	
	White blood cells		12/07/2001	7.3	
	White blood cells		19/07/2001	6.6	
	White blood cells		26/07/2001	8.4	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168334 **Seq:** 1 **Gender:** M
Reported: 20/08/2001 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 27/03/2001 **DOB:** 30/11/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyperhidrosis			 Clozaril ceased.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 16/08/1994 **Stopped:** CONTIN

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168375 **Seq:** 1 **Gender:** M
Reported: 12/09/2001 **Weight:**
Hospitalisation: **Age:** 46Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrasystoles		Supraventricular ectopic.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168376 **Seq:** 1 **Gender:** F
Reported: 12/09/2001 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 23/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Diarrhoea Electrocardiogram abnormal Palpitations Pyrexia Vomiting			

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified psychosis
Tablet 0.0 Oral
Batch: **Started:** 09/08/2001 **Stopped:** 24/08/2001

CIPRAMIL (Suspected) **Reason:** Depression
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 24/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168448 **Seq:** 1 **Gender:** M
Reported: 14/09/2001 **Weight:** 0.00
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 16/10/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Testis cancer	Caused or prolonged inpatient hospitalisation	Metastatic testicular carcinoma	Cisplatin, etoposide and GCSF

Medicine Details:

CLOZARIL (Suspected) **Reason:**
600.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168449 **Seq:** 1 **Gender:** F
Reported: 14/09/2001 **Weight:** 0.00
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 16/10/1951
Outcome: Unrelated death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Lymphoma Neutropenia			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
0.0 Oral
Batch: **Started:** 11/07/1996 L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Neutrophils		22/05/2006	1.4	
17/12/2002	Neutrophils		22/05/2006	0.9	
17/12/2002	White blood cells		22/05/2006	2.40	
17/12/2002	White blood cells		22/05/2006	3.10	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168450 **Seq:** 1
Reported: 14/09/2001
Hospitalisation: Admitted to hospital
Onset Date: 24/08/2001
Outcome: Recovered

Gender: F
Weight:
Age: 31
DOB: 24/07/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Chills Neuroleptic malignant syndrome Orthostatic hypotension Tachycardia		Temperature of 39.5 degrees.	Admitted to hospital.

Medicine Details:

HALOPERIDOL (Suspected) **Reason:** Unspecified schizophrenia
2.5 Milligram As necessary
Batch: **Started:** 25/07/2001 **Stopped:** 12/08/2001

CLOZARIL (Suspected) **Reason:**
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 10/08/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was ongoing, but the patient had subsequently ceased therapy.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168460 **Seq:** 1 **Gender:** M
Reported: 17/09/2001 **Weight:**
Hospitalisation: **Age:** 46
Onset Date: 28/08/2001 **DOB:** 15/03/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Life threatening	Life threatening.	Clozapine ceased.
Extrasystoles	Life threatening	Life threatening.	

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug) **Reason:** Depression
20.0 Milligram Daily
Batch: **Started:** 28/08/2001 **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
650.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** 07/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Low ventricular ejection fraction (40%).

Additional Information:

Possible long term (not unexpected reaction).

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168598 **Seq:** 1 **Gender:** M
Reported: 12/09/2001 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 03/09/2001 **DOB:** 19/06/1971
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cyanosis Deep vein thrombosis Drug level increased Dyspnoea Pulmonary embolism Syncope			

Medicine Details:

CLOZAPINE (Suspected)			**Reason:** Schizophrenia	
Tablet	500.0	Milligram	Daily	Oral
Batch:	**Started:** 01/12/2000			**Stopped:** 03/09/2001
CITALOPRAM HYDROBROMIDE (Suspected)			**Reason:**	
Tablet	60.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
CELECOXIB (Suspected)			**Reason:**	
	600.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Autopsy: the pulmonary blood vessels were totally occluded by thrombo-emboli. source of these was a deep vein thrombosis of the left leg. the coronary arteries were affected by marked arterosclerosis, features strongly suggestive of asthma. the toxological analysis revealed toxic blood levels of clozapine. the blood level of citalopram was within the toxic range.

Additional Information:

Patient died 09/01. cause of death: pulmonary embolism. history: obesity, sedentary life, coronary artery disease, schizophrenia, obsessive-complusive disorder, panic attacks, anxiety, tiredness, diabetes type ii.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168598 **Seq:** 1
Reported: 12/09/2001
Hospitalisation:
Onset Date: 03/09/2001
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 30
DOB: 19/06/1971
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)			**Reason:** Schizophrenia	
Tablet	500.0	Milligram	Daily	Oral
Batch:	**Started:** 01/12/2000			**Stopped:** 03/09/2001
CITALOPRAM HYDROBROMIDE (Suspected)			**Reason:**	
Tablet	60.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
CELECOXIB (Suspected)			**Reason:**	
	600.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				The cause of death is the combined effects of pulmonary thrombo-emboli and clozapine and citalopram toxicity. dvt of left calf; obesity; coronary artery disease. note clozapine level 7 mg/l, citalopram 0.3 mg/l.

Additional Information:

Patient died 09/01. cause of death: pulmonary embolism. history: obesity, sedentary life, coronary artery disease, schizophrenia, obsessive-complusive disorder, panic attacks, anxiety, tiredness, diabetes type ii.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168670 **Seq:** 1 **Gender:** F
Reported: 20/08/2001 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 18/07/2001 **DOB:** 03/12/1959
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			Treated with granular colonising stimulating factor and prophylactic antibiotics.

Medicine Details:

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

SODIUM VALPROATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 19/03/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		26/07/2001	0.73	
	White blood cells		26/07/2001	2.6	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168680 **Seq:** 1 **Gender:** M
Reported: 03/09/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 28/11/2000 **DOB:** 13/06/1979
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspepsia		Gastric acidity.	Ranitidine 300mg.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	400.0 Milligram	Daily	Oral
Batch:	**Started:** 01/11/1999	**Stopped:**	28/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dsate 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. patients psychosis is well controlled on clozaril.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168707 **Seq:** 1 **Gender:** M
Reported: 27/09/2001 **Weight:**
Hospitalisation: **Age:** 16
Onset Date: 07/09/2001 **DOB:** 08/12/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased		C-reactive protein increased	
Pyrexia		Spiking fevers.	
Cardiac enzymes increased			
Fatigue			
Influenza like illness			
Malaise			
Myocarditis			Clozaril ceased.

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
0.0
Batch: **Started:** 16/11/2000 **Stopped:** 11/09/2001

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 23/08/2001 **Stopped:** 06/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	C-Reactive Protein		07/09/2001	-	
	C-Reactive Protein		08/09/2001	106	
	C-Reactive Protein		18/09/2001	5.1	
	C-Reactive Protein		10/09/2001	88	
	C-Reactive Protein		20/09/2001	5.2	
	Creatine		07/09/2001	684	
	Creatine		08/09/2001	684	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168707 **Seq:** 1 **Gender:** M
Reported: 27/09/2001 **Weight:**
Hospitalisation: **Age:** 16
Onset Date: 07/09/2001 **DOB:** 08/12/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
0.0
Batch: **Started:** 16/11/2000 **Stopped:** 11/09/2001

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 23/08/2001 **Stopped:** 06/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase		10/09/2001	421	
	Creatine phosphokinase		18/09/2001	220	
	Creatine phosphokinase		20/09/2001	189	
	Other data				12/9/01 echocardiogram showed normal left ventricular size and function, satisfactory doppler filing profile, no resting regional wall motion abnormalities, ejection fraction 73%.
	Troponin		07/09/2001	0.27	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168707 **Seq:** 1 **Gender:** M
Reported: 27/09/2001 **Weight:**
Hospitalisation: **Age:** 16
Onset Date: 07/09/2001 **DOB:** 08/12/1984
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:** 16/11/2000		**Stopped:** 11/09/2001
ALCOHOL (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	Unspecified schizophrenia
Tablet	250.0 Milligram	Daily	Oral
Batch:	**Started:** 23/08/2001		**Stopped:** 06/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin		08/09/2001	0.95	
	Troponin		10/09/2001	-	
	Troponin		18/09/2001	-	
	Troponin		20/09/2001	-	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168708 **Seq:** 1
Reported: 27/09/2001
Hospitalisation: Admitted to hospital
Onset Date: 03/09/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 28
DOB: 22/01/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia Pancytopenia Respiratory depression		Bilateral pneumonia.	Vancomycin, ceftriaxone and epilim. patient transferred to intensive care unit. clozaril dose was reduced to 250mg then discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 750.0 Milligram Daily Oral

Batch: **Started:** 02/09/1999 **Stopped:** 14/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin		03/09/2001	90	
	Platelets		03/09/2001	60	
	White blood cells				3/9/2001: wbc dropped to a lowest level of 2.4.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168709 **Seq:** 1
Reported: 27/09/2001
Hospitalisation: Treated in outpatient department only.
Onset Date: 26/06/2001
Outcome: Recovered

Gender: M
Weight: 40.00
Age: 18Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Neutropenia Orthostatic hypotension Tachycardia			Mylanta for chest pain. patient was being treated as an outpatient.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 26/06/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				An electrocardiogram (ecg) and echocardiogram were normal.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168710 **Seq:** 1
Reported: 27/09/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/08/2001
Outcome: Recovered

Gender: F
Weight:
Age: 29
DOB: 19/10/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure.	Patient was hospitalised for 2 days. clozaril ceased.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 28/05/2001 **Stopped:** 01/09/2001

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking illicit drugs.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168711 **Seq:** 1 **Gender:** F
Reported: 27/09/2001 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: 14/08/2001 **DOB:** 17/09/1956
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Hypertrophic obstructive cardiomyopathy.	Clozaril ceased.

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 17/11/1995 **Stopped:** 05/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Echocardiogram (date not specified) revealed abnormal functioning of the left ventricle.

Additional Information:

Past history of a heart murmur prior to commencing clozaril.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168734 **Seq:** 1 **Gender:** F
Reported: 28/09/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 17/08/2001 **DOB:** 24/02/1972
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Neutropenia			

Medicine Details:

SALBUTAMOL SULFATE (Other drug) **Reason:**
Inhalation 0.0 Inhalation
Batch: **Started:** 06/08/2001 **Stopped:** CONTIN

BENZTROPINE MESYLATE (Other drug) **Reason:**
1.0 Milligram Daily
Batch: **Started:** 26/07/2001 **Stopped:** CONTIN

RISPERIDONE (Other drug) **Reason:**
Tablet 4.0 Milligram Daily Oral
Batch: **Started:** 26/07/2001 **Stopped:** CONTIN

BUDESONIDE (Other drug) **Reason:**
Inhalation 800.0 Microgram Daily Inhalation
Batch: **Started:** 06/08/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase	30-190	25/07/2001	437	
	Creatine phosphokinase	30-190	28/07/2001	128	
	Neutrophils		28/07/2001	1.7	
	Neutrophils		17/07/2001	1.4	
	Neutrophils		05/09/2001	3.6	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168734 **Seq:** 1 **Gender:** F
Reported: 28/09/2001 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 17/08/2001 **DOB:** 24/02/1972
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)			**Reason:**	
Tablet	400.0	Milligram	Daily	Oral
Batch:	**Started:** 02/07/2001		**Stopped:**	25/07/2001

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168735 **Seq:** 1 **Gender:** M
Reported: 24/08/2001 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 31/12/1996 **DOB:** 17/12/1943
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pollakiuria Salivary hypersecretion		Increased urinary frequency.	No treatment necessary as yet.

Medicine Details:

HALOPERIDOL (Other drug) **Reason:**
5.0 Milligram Daily
Batch: **Started:** **Stopped:**

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 01/01/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year. the dose start date for clozaril is not necessarily accurate but indicates the drug was started sometime in the month. the patient has residual urine after micturation and may have prostate trouble. the patient uses 6the toilet every 20 minutes.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168828 **Seq:** 1 **Gender:** F
Reported: 02/10/2001 **Weight:**
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 24/03/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder			Patient was hospitalised.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
150.0 Milligram Daily
Batch: **Started:** 07/09/2001 **Stopped:** 26/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168865 **Seq:** 1
Reported: 04/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 12/09/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 28
DOB: 20/08/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Dyspnoea Hepatic function abnormal Nausea Vomiting		Left vq pain.	 Patient was hospitalised. clozapine ceased. haloperidol initiated.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
200.0 Milligram Daily
Batch: **Started:** 26/10/2000 **Stopped:** 17/09/2001

ZOTON (Suspected) **Reason:** Other diseases of esophagus
30.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT				Alt 1200.
	AST = SGOT				Ast 540.
	Bilirubin				Bili total 48.
	GGT = SGGT =				Gamma gt 720.
	SAP = ALP				Alk phos 323.

Additional Information:

Sequelae: decreasing lft's since clozapine stopped. patient had been taking clozapine since october last year at this dose.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168932 **Seq:** 1 **Gender:** M
Reported: 04/10/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/05/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Dyspnoea Fatigue			Clozaril discontinued and commenced quetiapine.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				2 x ultrasounds: 49% and 51% ejection fraction.
	Troponin				Troponin i and creatine kinase (ck-mb) normal.

Additional Information:

The dose start date for clozaril is not accurate but indicates the drug was commenced sometime in 1998.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168933 **Seq:** 1 **Gender:** M
Reported: 04/10/2001 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 15/01/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutrophils levels have decreased due to chemo.	
Multiple myeloma			Treated with chemotherapy (not specified). patient will continue to receive clozaril with additional monitoring.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 21/03/2000 **Stopped:** 16/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		09/05/2000	4.3	
	Neutrophils		19/09/2001	1.30	
	White blood cells		09/05/2000	7.3	
	White blood cells		19/09/2001	3	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168935 **Seq:** 1
Reported: 04/10/2001
Hospitalisation: Hospitalisation prolonged
Onset Date: 01/01/2001
Outcome: Unrelated death 22/11/2001

Gender: M
Weight: 0.00
Age: 67
DOB: 27/03/1933
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Adrenal carcinoma	Caused or prolonged inpatient hospitalisation	Adrenal cancer	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Paralysis agitans
12.5 Milligram Daily Oral
Batch: **Started:** 27/02/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year. patient died 22/11/01.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168952 **Seq:** 1 **Gender:** F
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 16
Onset Date: 26/09/2001 **DOB:** 25/11/1984
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Life threatening.	Date of recovery 01/10/2001.

Medicine Details:

CENTRUM TABLETS (Other drug) **Reason:**
Tablet 1.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
175.0 Milligram Daily
Batch: **Started:** 11/07/2001 **Stopped:** 27/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168975 **Seq:** 1 **Gender:** M
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: **DOB:** 03/03/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia	Severe	Muscle jerking.	
Confusional state	Severe	Speech confused.	
Agitation	Severe		
Anxiety	Severe		
Choking	Severe		
Coordination abnormal	Severe		
Drug level increased	Severe		Dose of clopine was reduced by 200mg/day from 700mg nocte on 21/8/2001.
Dyspnoea	Severe		

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 31/05/2001 **Stopped:** 21/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				The patient's serum clozapine levels on 8/8/2001 (whilst on 700mg clopine) was 4.59umol/l. serum clozapine on 700mg clozaril on 15/12/1997 was 2.46umol/l. repeat serum clozapine levels on 23/8/2001 in a different lab was 2059ug/l.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168977 **Seq:** 1 **Gender:** F
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 22/09/2001 **DOB:** 11/11/1961
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Clopine ceased.

Medicine Details:

CLOPINE (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	162.5 Milligram		Total	Oral
Batch:	**Started:** 20/09/2001		**Stopped:** 23/09/2001	
HALOPERIDOL (Suspected)			**Reason:** Unspecified neurosis	
Injection	5.0 Milligram		As necessary	Intramuscular
Batch:	**Started:** 20/09/2001		**Stopped:** 24/09/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	1-40	22/09/2001	253	
	ALT = SGPT	1-40	24/09/2001	385	
	AST = SGOT	1-30	22/09/2001	-	
	AST = SGOT	1-30	24/09/2001	189	
	GGT = SGGT =	1-25	22/09/2001	341	
	GGT = SGGT =	1-25	24/09/2001	322	
	SAP = ALP	25-100	22/09/2001	-	

Additional Information:

Previously raised lft's following olanzapine and epilim. the patient is hep c positive and hep c rna positive.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 168977 **Seq:** 1
Reported: 05/10/2001
Hospitalisation:
Onset Date: 22/09/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 39
DOB: 11/11/1961
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	162.5 Milligram		Total	Oral
Batch:	**Started:** 20/09/2001		**Stopped:** 23/09/2001	
HALOPERIDOL (Suspected)			**Reason:** Unspecified neurosis	
Injection	5.0 Milligram		As necessary	Intramuscular
Batch:	**Started:** 20/09/2001		**Stopped:** 24/09/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	25-100	24/09/2001	254	

Additional Information:

Previously raised lft's following olanzapine and epilim. the patient is hep c positive and hep c rna positive.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169031 **Seq:** 1 **Gender:** M
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: **DOB:** 06/08/1978
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Testicular disorder		Testicular cancer	

Medicine Details:

HALDOL DECANOATE (Other drug) **Reason:**
Injection 0.0 Intravenous
Batch: **Started:** L TERM **Stopped:**

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

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

PEPCIDINE (Other drug) **Reason:**
20.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169031 **Seq:** 1 **Gender:** M
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: **DOB:** 06/08/1978
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	600.0 Milligram	Daily	Oral	
Batch:	**Started:** 16/05/1996		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169032 **Seq:** 1 **Gender:** M
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 18/09/2001 **DOB:** 09/11/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Neutropenia			Growth stimulating factor

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 19/04/2001 **Stopped:** 04/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		19/04/2001	3	
	Neutrophils		17/09/2001	0.59	
	White blood cells		19/04/2001	4.9	
	White blood cells		17/09/2001	2.7	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169035 **Seq:** 1 **Gender:** M
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: 28/06/2001 **DOB:** 12/02/1958
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Clozaril discontinued.

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
3.5 Gram Daily
Batch: **Started:** L TERM **Stopped:**

THYROXINE SODIUM (Other drug) **Reason:**
300.0 Microgram Daily
Batch: **Started:** L TERM **Stopped:**

CALCITRIOL (Other drug) **Reason:**
750.0 Microgram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 525.0 Milligram Daily Oral
Batch: **Started:** 26/02/2000 **Stopped:** 15/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				22/2/00: echocardiogram normal, 2/11/00: echocardiogram showed mildly dilated left ventricle; 9/5/01: echocardiogram showed mildly dilated left ventricle with moderate global systolic dysfunction; ejection fraction = 30%; concluded that left ventricular function had deteriorated since the echocardiogram report of nov 2000.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. patient had a thyroidectomy in 1999. family history of heart disease (coronary). patient was a smoker and had been treated for hyperlipidaemia and hypertension.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169123 **Seq:** 1 **Gender:** M
Reported: 04/10/2001 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: 10/08/2001 **DOB:** 28/02/1950
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		Heart attack	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 28/02/1996 **Stopped:** 10/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking hypertension medication. autopsy report received: the patient died on 10 august 2001. cause of death was 1) left ventricular failure, 2) hypertension and 3) morbid obesity.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169124 **Seq:** 1 **Gender:** M
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 21/08/2001 **DOB:** 10/11/1943
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death		Died in his sleep	Date of death 21/08/01.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 275.0 Milligram Daily Oral
Batch: **Started:** 14/12/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Autopsy was inconclusive.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169125 **Seq:** 1 **Gender:** M
Reported: 04/10/2001 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 11/09/2001 **DOB:** 18/10/1953
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia			Date of death 11/09/01

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 24/07/2001 **Stopped:** 11/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking many medications (unspecified).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169142 **Seq:** 1 **Gender:** M
Reported: 15/10/2001 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: 13/08/2001 **DOB:** 19/09/1977
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			

Medicine Details:

TAMIFLU (Suspected) **Reason:** Otr&nos infec&parasit diseases
Oral application 150.0 Milligram Daily Oral
Batch: **Started:** 10/08/2001 **Stopped:** 14/08/2001

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 05/07/2000 **Stopped:** 15/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		13/08/2001	1.6	
	Neutrophils		15/08/2001	1.2	
	White blood cells		13/08/2001	3.2	
	White blood cells		15/08/2001	3.1	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169151 **Seq:** 1
Reported: 15/10/2001
Hospitalisation: Hospitalisation prolonged
Onset Date: 20/09/2001
Outcome: Recovered

Gender: M
Weight:
Age: 24
DOB: 18/04/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation Syncope			Patient was an inpatiet. prolonged hospitalisation. given intravenous amiodarone.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 05/03/2001 **Stopped:** 21/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				27/9/01 echo normal, cardiac enzymes normal.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169152 **Seq:** 1
Reported: 15/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 15/09/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 64
DOB: 22/02/1937
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Confusional state Pyrexia	Life threatening	Life threatening.	Clozaril ceased. patient hospialised 17/09/2001. given dantrolene.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 03/09/2001 **Stopped:** 17/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Creatinine kinase (ck) levels raised.

Additional Information:

Patient had suffered mild renal impairment.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169184 **Seq:** 1 **Gender:** M
Reported: 12/10/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 08/10/2001 **DOB:** 28/04/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Ceased clopine

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 27/04/2001 **Stopped:** 08/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/02/2001	4.8	
	Neutrophils		27/04/2001	3.8	
	Neutrophils		01/06/2001	2.5	
	Neutrophils		27/06/2001	3.5	
	Neutrophils		08/10/2001	1.3	
	Neutrophils		04/10/2001	1.5	
	Neutrophils		21/06/2001	2.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169184 **Seq:** 1 **Gender:** M
Reported: 12/10/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 08/10/2001 **DOB:** 28/04/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)			**Reason:**	
Tablet	300.0 Milligram		Daily	Oral
Batch:	**Started:** 27/04/2001		**Stopped:**	08/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		25/07/2001	3.0	
	White blood cells		22/02/2001	7.9	
	White blood cells		27/04/2001	7.2	
	White blood cells		01/06/2001	5.5	
	White blood cells		27/06/2001	6.8	
	White blood cells		25/07/2001	6.2	
	White blood cells		21/06/2001	5.7	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169184 **Seq:** 1 **Gender:** M
Reported: 12/10/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 08/10/2001 **DOB:** 28/04/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)			**Reason:**	
Tablet	300.0 Milligram		Daily	Oral
Batch:	**Started:** 27/04/2001		**Stopped:**	08/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		04/10/2001	5.1	
	White blood cells		08/10/2001	5.4	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169215 **Seq:** 1 **Gender:** M
Reported: 10/09/2001 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 28/07/2001 **DOB:** 26/03/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly Cardiomyopathy Chest pain Dyspnoea		Left ventricular hyperthrophy.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 550.0 Milligram Daily Oral
Batch: **Started:** 01/02/2000 **Stopped:** 28/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Echocardiogram has not shown an improvement in cardiac function.

Additional Information:

The dose start and stop date is not necessarily accurate but indicates the dru g was started and stopped sometime in the month. the date of onset is not necessarily accurate but indicates onset sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169216 **Seq:** 1 **Gender:** M
Reported: 10/09/2001 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 28/07/2001 **DOB:** 26/03/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Suicide attempt			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	550.0 Milligram	Daily	Oral
Batch:	**Started:** 01/02/2000	**Stopped:**	28/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169218 **Seq:** 1 **Gender:** U
Reported: 14/09/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** 01/06/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Ggt - 10 times upper limit of normal, alt - 10 times upper limit of normal sap - marginally high.

Additional Information:

P/h of hepatitis c. the dose start date is not necessarily accurate but indicates the drug was sta rted sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169228 **Seq:** 1
Reported: 17/10/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 37
DOB: 29/09/1964
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Clozaril discontinued. patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 450.0 Milligram Daily Oral

Batch: **Started:** 26/04/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169238 **Seq:** 1
Reported: 19/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/10/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 26/07/1961
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Clozaril discontinued and undergoing daily blood tests. hospitalised and commenced on g-csf, risperdal, bromocryptine and phenytoin.
Confusional state			
Convulsion			
Malaise			
Pyrexia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 16/05/2001 **Stopped:** 01/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				An eeg performed on 7/10/01 showed that focal right sided epilepsy was the cause of the fitting.
	Neutrophils		01/10/2001	0.2	
	Neutrophils		03/10/2001	0.1	
	Neutrophils		02/10/2001	0.10	
	Neutrophils		04/10/2001	<0.1	
	Neutrophils		06/10/2001	<0.1	

Additional Information:

The patient was also receiving antibiotics.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169238 **Seq:** 1
Reported: 19/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/10/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 26/07/1961
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 16/05/2001 **Stopped:** 01/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		08/10/2001	<0.1	
	Neutrophils		10/10/2001	0.7	
	Neutrophils		11/10/2001	4.6	
	Neutrophils		09/10/2001	0.8	
	Neutrophils		07/10/2001	0.1	
	Neutrophils		05/10/2001	<0.1	
	White blood cells		01/10/2001	1.2	

Additional Information:

The patient was also receiving antibiotics.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169238 **Seq:** 1
Reported: 19/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/10/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 26/07/1961
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 16/05/2001 **Stopped:** 01/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		02/10/2001	0.85	
	White blood cells		03/10/2001	1.1	
	White blood cells		04/10/2001	0.6	
	White blood cells		05/10/2001	0.3	
	White blood cells		06/10/2001	0.8	
	White blood cells		07/10/2001	0.6	
	White blood cells		08/10/2001	1.1	

Additional Information:

The patient was also receiving antibiotics.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169238 **Seq:** 1
Reported: 19/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/10/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 26/07/1961
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 16/05/2001 **Stopped:** 01/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		09/10/2001	2.5	
	White blood cells		10/10/2001	2.6	
	White blood cells		11/10/2001	7.8	

Additional Information:

The patient was also receiving antibiotics.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169239 **Seq:** 1 **Gender:** M
Reported: 19/10/2001 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 28/09/2001 **DOB:** 12/10/1979
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 25/10/2000 **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 month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169240 **Seq:** 1
Reported: 19/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2001
Outcome: Unknown

Gender: M
Weight:
Age: 29
DOB: 08/02/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Cardiac disorder		Ventricular dilation.	The patient was being monitored in hospital.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 29/02/1996 **Stopped:** 28/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		29/02/1996	8.1	
	Neutrophils		04/09/2001	4.3	

Additional Information:

"cardiac problems" on echocardiogram, possible cardiomyopathy. the dose stop date is not necessarily accurate but indicates the drug was ceased sometime in october 2001.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169240 **Seq:** 1
Reported: 19/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2001
Outcome: Unknown

Gender: M
Weight:
Age: 29
DOB: 08/02/1972
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	500.0 Milligram	Daily		Oral
Batch:	**Started:** 29/02/1996		**Stopped:**	28/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Echocardiography done on 6/9/02: diagnosis = mild left ventricular dilation with moderate global impairment, no significant valvular abnormality and no other structural or haemodynamic abnormality detected. comments = left ventricle at rest: systolic function was moderately impaired, segmental function was uniformly hypokinetic, dimensions were mildly dilated.
	White blood cells		29/02/1996	13	

Additional Information:

"cardiac problems" on echocardiogram, possible cardiomyopathy. the dose stop date is not necessarily accurate but indicates the drug was ceased sometime in october 2001.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169240 **Seq:** 1
Reported: 19/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2001
Outcome: Unknown

Gender: M
Weight:
Age: 29
DOB: 08/02/1972
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 29/02/1996 **Stopped:** 28/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		04/09/2001	7.8	

Additional Information:

"cardiac problems" on echocardiogram, possible cardiomyopathy. the dose stop date is not necessarily accurate but indicates the drug was ceased sometime in october 2001.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169241 **Seq:** 1 **Gender:** M
Reported: 19/10/2001 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: **DOB:** 30/08/1978
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Electrocardiogram abnormal Eosinophilia		Light tachycardia.	Admitted to hospital. clozaril was discontinued as a measure to treat the reaction.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 125.0 Milligram Daily Oral
Batch: **Started:** 13/09/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Ecg - showed abnormal st changes on the inferior lead and t-wave inversion,

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169242 **Seq:** 1 **Gender:** F
Reported: 19/10/2001 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 02/08/2001 **DOB:** 31/08/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoxia		Oxygen saturation of 75%	
Consciousness fluctuating			Clozaril temporarily discontinued. clozaril was reinitiated at 12.5mg/bd.
Dystonia			
Salivary hypersecretion			

Medicine Details:

CLOZARIL (Interaction)				**Reason:**	Unspecified schizophrenia
Tablet	300.0	Milligram	Daily		Oral
Batch:	**Started:** 02/07/1997			**Stopped:**	31/07/2000
MORPHINE SULPHATE (Interaction)				**Reason:**	Pain
Injection	60.0	Milligram	Daily		Intravenous
Batch:	**Started:**		L TERM	**Stopped:**	
ORPHENADRINE CITRATE (Interaction)				**Reason:**	Pain
Tablet	50.0	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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169245 **Seq:** 1 **Gender:** M
Reported: 19/10/2001 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 05/10/2001 **DOB:** 04/06/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 550.0 Milligram Daily Oral

Batch: **Started:** 17/04/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169281 **Seq:** 1 **Gender:** F
Reported: 19/10/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 01/10/2001 **DOB:** 07/07/1944
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia			Ceased clozaril.

Medicine Details:

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

MIRTAZAPINE (Other drug) **Reason:**
30.0 Milligram Daily
Batch: **Started:** 01/09/2001 **Stopped:**

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 24/09/2001 **Stopped:** 01/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils	(0-0.5)	01/10/2001	3.7	
	Eosinophils	(0-0.5)	03/10/2001	3.6	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169311 **Seq:** 1
Reported: 22/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 29/09/2001
Outcome: Unknown

Gender: M
Weight:
Age: 37
DOB: 22/10/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Colitis ulcerative Thrombophlebitis			 Warfarin. patient hospitalised

Medicine Details:

FLAGYL (Suspected)			**Reason:**			
Oral application	0.0			Oral		
Batch:	**Started:**			**Stopped:**		
CLOZAPINE (Suspected)			**Reason:**			
Tablet	200.0	Milligram	Daily	Oral		
Batch:	**Started:**			**Stopped:**	28/09/2001	5Y

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Concomitant disease: malabsorption syndrome.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169312 **Seq:** 1
Reported: 22/10/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 38
DOB: 22/10/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Hyperhidrosis Pyrexia			Given heparin 5000 units bd. admitted to psychiatric unit. clozapine to be recommenced.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 28/09/2001 5Y

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				Wbc - 12.5, neu - 10.2, monocytes - 0.9, pt-24.9 (13.17 sec), inr - 2.24, aptt - 31.6 (24.37).

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169313 **Seq:** 1
Reported: 22/10/2001
Hospitalisation: Admitted to hospital
Onset Date: 15/10/2001
Outcome: Recovered

Gender: F
Weight:
Age: 32
DOB: 14/07/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness Fatigue Hypotension Leukopenia Neutropenia Tachycardia			Clozapine ceased. referred to a haemotologist for assessment.

Medicine Details:

TEMAZEPAM (Other drug)			**Reason:** Specific disorders of sleep	
Oral application	10.0 Milligram	Daily	Oral	
Batch:	**Started:** 15/08/2001		**Stopped:**	CONTIN
CLOZAPINE (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	**Started:** 27/08/2001		**Stopped:** 15/10/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		15/10/2001	1.2	
	Neutrophils		17/10/2001	0.4	
	Neutrophils		18/10/2001	0.21	
	White blood cells		15/10/2001	2.9	
	White blood cells		17/10/2001	2.0	
	White blood cells		18/10/2001	1.9	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169395 **Seq:** 1 **Gender:** M
Reported: 29/10/2001 **Weight:**
Hospitalisation: **Age:** 51
Onset Date: 08/10/2001 **DOB:** 24/04/1950
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 11/10/2000 **Stopped:** 28/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month. no previous history of drug-induced neutropenia or bone marrow disorder.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169396 **Seq:** 1 **Gender:** F
Reported: 29/10/2001 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 09/10/2001 **DOB:** 14/07/1954
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction			Cardiopulmonary resuscitation.

Medicine Details:

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

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

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

BENZTROPINE MESYLATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month. no previous history of drug-induced neutropenia or bone marrow disorders. obesity.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169396 **Seq:** 1
Reported: 29/10/2001
Hospitalisation:
Onset Date: 09/10/2001
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 47
DOB: 14/07/1954
Causality: Causality possible

Reaction Details:

Medicine Details:

PHOLCODINE (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**			**Stopped:**
CLOZARIL (Suspected)			**Reason:**	
Tablet	400.0	Milligram	Daily	Oral
Batch:	**Started:** 02/05/2001			**Stopped:**

Laboratory Investigations:

Additional Information:

The dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month. no previous history of drug-induced neutropenia or bone marrow disorders. obesity.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169493 **Seq:** 1 **Gender:** M
Reported: 29/10/2001 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 28/05/2001 **DOB:** 16/02/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 11/05/1998 **Stopped:** 28/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				5/5/01:cardiology report:left ventricle (lv) diastolic 4.8cm (normal <5.2), lv systolic 3.6cm, lv shortening 25%(normal 28%), aortic root 4.0cm (normal <3.7), left atrium 4.1cm (normal <4.0), iv septum 1.2cm (normal <1.1), posterior wall 1.0cm (normal <1.1), lv wall motion normal grade 1 (estimated ef>59%), mitral valve regurgitation trivial, aortic valve regurgitation nil,

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month. history of alcohol use.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169493 **Seq:** 1 **Gender:** M
Reported: 29/10/2001 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 28/05/2001 **DOB:** 16/02/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	300.0 Milligram	Daily	Oral
Batch:	**Started:** 11/05/1998	**Stopped:**	28/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Tricuspid regurgitation nil, pulmonary regurgitation nil, e/a 0.7/0.9, isovolumic relation time (ivrt) 72ms, dt 119ms,pat 96ms, borderline concentric left ventricular hypertrophy, normal left ventricular size with low normal systolic function, mild left atrial enlargement, mildly thickened aortic valve with good cusp excursion, mild aortic root enlargement, mildly thickened

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month. history of alcohol use.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169493 **Seq:** 1 **Gender:** M
Reported: 29/10/2001 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 28/05/2001 **DOB:** 16/02/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	300.0 Milligram	Daily	Oral
Batch:	**Started:** 11/05/1998	**Stopped:**	28/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Mitral valve leaflets with normal valve opening, normal right sided chambers and valves. comment: borderline left ventricular function.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month. history of alcohol use.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169568 **Seq:** 1 **Gender:** M
Reported: 27/09/2001 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 26/06/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Delirium Hyperhidrosis			

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 21/06/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Self-medicating with other unknown medictions. the patient's dose had gradually been increased by 25mg daily, reaching 100mg daily on 26.6.01. for the 2 nights that the patient was on 100mg, he experienced the reactions one hour after the dose. this settled down promptly when the dose was stopped for one day, then reduced to 50mg daily.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169574 **Seq:** 1 **Gender:** M
Reported: 31/10/2001 **Weight:** 70.00
Hospitalisation: **Age:** 40
Onset Date: 04/10/2001 **DOB:** 26/07/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			Clozapine ceased. treated with anti-epileptic. date of recovery.
Convulsion			
Neutropenia			
Pyrexia			

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169577 **Seq:** 1 **Gender:** F
Reported: 31/10/2001 **Weight:**
Hospitalisation: **Age:** 32Y
Onset Date: 16/10/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
300.0 Milligram Daily
Batch: **Started:** 07/08/2001 **Stopped:** 16/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		09/10/2001	4.9	
	Neutrophils		16/10/2001	1.16	
	Neutrophils		24/10/2001	0.0	
	Neutrophils		18/10/2001	0.21	
	White blood cells		09/10/2001	7	
	White blood cells		16/10/2001	2.9	
	White blood cells		18/10/2001	1.9	

Additional Information:

Patient history of amphetamine abuse.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169715 **Seq:** 1 **Gender:** M
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 28/07/2001 **DOB:** 09/01/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pollakiuria			Treated with oxybutynin.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 450.0 Milligram Daily Oral

Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for clozaril is not accurate but indicates the drug was started sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169783 **Seq:** 1
Reported: 07/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 09/10/2001
Outcome: Recovered

Gender: F
Weight:
Age: 34
DOB: 18/06/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Patient took an overdose of clozaril.	Patient hospitalised, icu. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 04/07/2001 **Stopped:** 09/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169784 **Seq:** 1 **Gender:** F
Reported: 07/11/2001 **Weight:** 52.00
Hospitalisation: **Age:** 83
Onset Date: 28/10/2001 **DOB:** 15/09/1918
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			
Fall			Patient hospitalised. temporary discontinuation of clozaril. treated with gentamycin.
Somnolence			
Weight decreased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 10/10/2000 **Stopped:** 17/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Albumin	35 - 52	16/10/2001	16	
	C-Reactive Protein	0 - 10	16/10/2001	130	
	Haemoglobin	115 - 155	16/10/2001	109	
	Mid-stream urine				16/10/01: urine culture showed klebsiella pneumoniae.

Additional Information:

Sequeale: neurological disorder, presumed closed head injury. the date of onset is not necessarily accurate but indicates onset sometime in the month. history: dermentia.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169784 **Seq:** 1
Reported: 07/11/2001
Hospitalisation:
Onset Date: 28/10/2001
Outcome: Unknown

Gender: F
Weight: 52.00
Age: 83
DOB: 15/09/1918
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 10/10/2000 **Stopped:** 17/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Ct scan of brain showed generalised supratentorial cerebral atrophy with more focal atrophy involving the left temporal lobe. bilateral basal ganglia calcification (conclusion: cerebral atrophy).
	White blood cells	4.5 - 11.5	16/10/2001	13 & 14	

Additional Information:

Sequeale: neurological disorder, presumed closed head injury. the date of onset is not necessarily accurate but indicates onset sometime in the month. history: dermentia.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169785 **Seq:** 1
Reported: 07/11/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 28
DOB: 05/04/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection Convulsion Hyponatraemia Leukopenia Syncope		Not otherwise specified.	Patient was intubated. patient was hospitalised. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 03/04/2001 **Stopped:** 14/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		03/04/2001	5	3.4.01 - pre-treatment.
	Neutrophils		15/10/2001	7.20	3.4.01 - pre-treatment.
	White blood cells		03/04/2001	7.75	3.4.01 - pre-treatment. date unknown: wbc approxiamately 20x10?9/l.
	White blood cells		15/10/2001	10.50	3.4.01 - pre-treatment. date unknown: wbc approxiamately 20x10?9/l.

Additional Information:

The patient also had an infection (not specified).

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169786 **Seq:** 1 **Gender:** M
Reported: 07/11/2001 **Weight:**
Hospitalisation: **Age:** 62
Onset Date: 12/10/2001 **DOB:** 12/02/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Consciousness fluctuating Hypotension			Reaction resolving. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 525.0 Milligram Daily Oral
Batch: **Started:** 16/12/1996 **Stopped:** 12/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169851 **Seq:** 1
Reported: 08/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 21/10/2001
Outcome: Recovered

Gender: F
Weight:
Age: 25
DOB: 24/06/1976
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Blood creatine phosphokinase incr Blood pressure fluctuation Chest pain Hyperglycaemia Pyrexia Troponin increased		Suspected myocarditis	Clozaril ceased. admitted to hospital

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.5 Milligram Daily
Batch: **Started:** **Stopped:**

CLOPIXOL (Other drug) **Reason:**
600.0 Milligram Daily
Batch: **Started:** **Stopped:**

GLUCOPHAGE (Other drug) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 04/10/2001 **Stopped:**

ATROVENT (Other drug) **Reason:**
500.0 Microgram Daily
Batch: **Started:** 04/10/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				16/10/01: glucose rand= 11.9 mmol/l (nr 3.6 - 7.8) creatinine kinase = 1195 u/l (nr 16 - 139) glyco haemoglobin = 6.8% (nr 4.0 - 6.0)

Additional Information:

The patient was obese and had a past medical history of diabetes. no family history of heart disease and asthma.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169851 **Seq:** 1
Reported: 08/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 21/10/2001
Outcome: Recovered

Gender: F
Weight:
Age: 25
DOB: 24/06/1976
Causality: Causality possible

Reaction Details:

Medicine Details:

VENTOLIN (Other drug)		**Reason:**	
	5.0 Milligram	Daily	
Batch:	**Started:** 04/10/2001		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	Unspecified schizophrenia
Tablet	500.0 Milligram	Daily	Oral
Batch:	**Started:** 04/10/2001		**Stopped:** 19/10/2001

Laboratory Investigations:

Additional Information:

The patient was obese and had a past medical history of diabetes. no family history of heart disease and asthma.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169852 **Seq:** 1 **Gender:** F
Reported: 08/11/2001 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 18/10/2001 **DOB:** 23/10/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations Tachycardia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 50.0 Milligram Daily Oral

Batch: **Started:** 28/03/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169881 **Seq:** 1
Reported: 12/11/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight:
Age: 45
DOB: 12/04/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Severe	Severe urinary retention.	Patient hospitalised. clozaril ceased temporarily. given a catheterision.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 01/09/1998 L TERM **Stopped:** 28/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not necessarily accurate but inidcates clozaril was started sometime in the month. the dose stop date for the drug clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169882 **Seq:** 1
Reported: 12/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 21/10/2001
Outcome: Unknown

Gender: F
Weight:
Age: 62
DOB: 14/04/1939
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection Leukocytosis			Admitted to hospital.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 13/04/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169883 **Seq:** 1
Reported: 12/11/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 31
DOB: 17/06/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Patient hospitalised. given sodium valproate 800mg/day.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clozaril was reduced to 300mg.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169884 **Seq:** 1
Reported: 12/11/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 27
DOB: 10/04/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic neoplasm malignant Leukopenia Neutropenia			Clozaril ceased. measures taken included surgery for the liver cancer. admitted to hospital. discharged on the 30/10/2001.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 04/10/1996 **Stopped:** 29/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		27/10/2001	2.1X10.9/L	
	Neutrophils		29/10/2001	1.5X10.9/L	
	Neutrophils		30/10/2001	1.7X10.9/L	
	White blood cells		27/10/2001	2.72X10.9L	
	White blood cells		29/10/2001	2.4X10.9L	
	White blood cells		30/10/2001	2.55X10.9L	

Additional Information:

Patient experienced lamellar variant hepatoma in oct 1999.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169885 **Seq:** 1
Reported: 12/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/10/2001
Outcome: Recovered

Gender: M
Weight:
Age: 48
DOB: 07/08/1953
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism Syncope			Patient hospitalised. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 03/09/2001 **Stopped:** 28/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset and the dose stop date are not necessarly accurate but indicate that onset and stop date were both sometime in october. history of obesity and alcohol dependence

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169892 **Seq:** 1
Reported: 13/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 24/10/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 22
DOB: 01/09/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction	Severe		Patient was hospitalised and treated with insertion of nasogastric tube, enema x 2, and iv ceftriaxone and flagyl for 3 days.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 10/10/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Gastroschiesis with obstruction in infancy--surgery required at 5 years of age

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169904 **Seq:** 1 **Gender:** M
Reported: 12/11/2001 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 04/10/2001 **DOB:** 15/05/1942
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction Pulmonary oedema			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 07/10/1998 **Stopped:** 04/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The cause of death was suspected to be due to pulmonary oedema. an autopsy was not performed.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169937 **Seq:** 1 **Gender:** M
Reported: 14/11/2001 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: **DOB:** 15/10/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Heart rate over 140 beats per minute.	

Medicine Details:

HALOPERIDOL (Other drug)		**Reason:** Otr spec symp psychopathol nec		
Oral application	5.0 Milligram	As necessary	Oral	
Batch:	**Started:** 06/09/2001		**Stopped:**	
SODIUM VALPROATE (Other drug)		**Reason:**		
Oral application	1.4 Gram	Daily	Oral	
Batch:	**Started:** 25/09/2001		**Stopped:**	CONTIN
CLOZAPINE (Suspected)		**Reason:** Unspecified schizophrenia		
Tablet	500.0 Milligram	Daily	Oral	
Batch:	**Started:** 06/08/2001		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169949 **Seq:** 1 **Gender:** F
Reported: 15/10/2001 **Weight:** 48.00
Hospitalisation: **Age:** 27
Onset Date: 08/06/2001 **DOB:** 28/07/1973
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness Neutropenia			 Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 03/11/1999 **Stopped:** 08/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		08/06/2001	1.3	
	Neutrophils		15/06/2001	1	
	Neutrophils		18/06/2001	2.2	
	Neutrophils		19/06/2001	2.3	
	Neutrophils		29/06/2001	1.5	
	Neutrophils		22/06/2001	2.0	
	Neutrophils		21/06/2001	2.0	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169949 **Seq:** 1
Reported: 15/10/2001
Hospitalisation:
Onset Date: 08/06/2001
Outcome: Not yet recovered

Gender: F
Weight: 48.00
Age: 27
DOB: 28/07/1973
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 03/11/1999 **Stopped:** 08/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		20/06/2001	2.1	
	White blood cells		08/06/2001	5.1	
	White blood cells		15/06/2001	5	
	White blood cells		18/06/2001	4.8	
	White blood cells		19/06/2001	5.5	
	White blood cells		20/06/2001	4.1	
	White blood cells		21/06/2001	4.7	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169949 **Seq:** 1
Reported: 15/10/2001
Hospitalisation:
Onset Date: 08/06/2001
Outcome: Not yet recovered

Gender: F
Weight: 48.00
Age: 27
DOB: 28/07/1973
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	300.0 Milligram	Daily		Oral
Batch:	**Started:** 03/11/1999		**Stopped:**	08/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		22/06/2001	4.9	
	White blood cells		29/06/2001	4.3	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169950 **Seq:** 1 **Gender:** F
Reported: 15/10/2001 **Weight:** 48.00
Hospitalisation: **Age:** 27
Onset Date: 08/06/2001 **DOB:** 28/07/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Hallucination Paranoia Suicide attempt			Electroconvulsive therapy (ect).

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 03/11/1999 **Stopped:** 08/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169965 **Seq:** 1 **Gender:** M
Reported: 16/11/2001 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: 26/10/2001 **DOB:** 24/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain			
Dyspnoea			
Eosinophilia			
Fatigue			
Hypertension			
Influenza like illness			
Malaise			
Myocarditis			Clozaril stopped.
Tachycardia			
Troponin increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 09/10/2001 **Stopped:** 26/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine kinase MB		26/10/2001	45	
	Creatine kinase MB		27/10/2001	46	
	Haematology				26/10/2001 raised eosinophils, troponin = 0.7; 27/10/01 - troponin = 1.9
	Neutrophils		29/10/2001	11.10	
	Other data				Echocardiogram was normal except for small pericardial effusion.

Additional Information:

Other reaction terms - arthralgia, leucocytosis.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 169965 **Seq:** 1 **Gender:** M
Reported: 16/11/2001 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: 26/10/2001 **DOB:** 24/12/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	350.0 Milligram	Daily		Oral
Batch:	**Started:** 09/10/2001		**Stopped:**	26/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		29/10/2001	13.9	

Additional Information:

Other reaction terms - arthralgia, leucocytosis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170086 **Seq:** 1 **Gender:** M
Reported: 16/11/2001 **Weight:**
Hospitalisation: **Age:** 19
Onset Date: 26/10/2001 **DOB:** 08/12/1981
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 12.5 Milligram 1 time Oral

Batch: **Started:** 26/10/2001 **Stopped:** 26/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		29/10/2001	13.1	
	White blood cells		29/10/2001	17.2	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170138 **Seq:** 1
Reported: 21/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 05/11/2001
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 31
DOB: 18/12/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia	Caused or prolonged inpatient hospitalisation	Patient experienced hyperglycaemia and suspected ketoacidosis.	Receiving insulin. Clozaril had been reduced to 100mg daily.
Ketoacidosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 22/09/2000 **Stopped:** 27/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/11/2001	Serum glucose				

Additional Information:

Patient also taking Sodium Valproate.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170139 **Seq:** 1
Reported: 21/11/2001
Hospitalisation: Hospitalisation prolonged
Onset Date: 02/11/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 37
DOB: 26/06/1964
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		135 beats per minute.	Ceased effexor
Psychotic disorder	Severe	Severely psychotic	
Electrocardiogram abnormal			
Orthostatic hypotension			

Medicine Details:

EFEXOR (Suspected) **Reason:**
0.0
Batch: **Started:** 27/10/2001 **Stopped:** 02/11/2001

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 850.0 Milligram Daily Oral
Batch: **Started:** 13/11/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170140 **Seq:** 1 **Gender:** M
Reported: 21/11/2001 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 28/07/1998 **DOB:** 28/07/1946
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Sexual dysfunction	
Speech disorder		Tongue-tied speech	
Asthenia		Weak legs.	
Weight increased		Weight increased from 105kg to 150 kg.	
Drug ineffective			
Drug level increased			
Priapism			
Psychotic disorder			The patient is being treated as outpatient.
Salivary hypersecretion			
Sleep disorder			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 30/06/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates that onset was sometime in july 1998.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170208 **Seq:** 1 **Gender:** F
Reported: 19/10/2001 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 28/07/2001 **DOB:** 16/04/1944
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia			Clozaril discontinued.

Medicine Details:

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

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

CLONAZEPAM (Other drug) **Reason:**
3.5 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 125.0 Milligram Daily Oral
Batch: **Started:** 05/07/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils				0.8x10 9/l.

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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170388 **Seq:** 1
Reported: 28/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 19/11/2001
Outcome: Recovered

Gender: F
Weight: 70.00
Age: 46
DOB: 23/07/1955
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure acute			Patient was hospitalised. date of recovery 23.11.01.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
150.0 Milligram Daily
Batch: **Started:** 02/11/2001 **Stopped:**

RENITEC (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry	40-100	19/11/2001	27	Urea/cr
	Biochemistry	40-100	19/11/2001	29	Urea/cr
	Biochemistry	40-100	20/11/2001	39	Urea/cr
	Biochemistry	40-100	21/11/2001	49	Urea/cr
	Creatinine	1.15-0.10	19/11/2001	0.64	
	Creatinine	1.15-0.10	19/11/2001	0.54	
	Creatinine	1.15-0.10	21/11/2001	0.14	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170388 **Seq:** 1
Reported: 28/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 19/11/2001
Outcome: Recovered

Gender: F
Weight: 70.00
Age: 46
DOB: 23/07/1955
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
150.0 Milligram Daily
Batch: **Started:** 02/11/2001 **Stopped:**

RENITEC (Suspected) **Reason:**
5.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatinine	1.15-0.10	20/11/2001	0.29	
	Urea	3-8	19/11/2001	17	
	Urea	3-8	19/11/2001	15.8	
	Urea	3-8	20/11/2001	11.2	
	Urea	3-8	21/11/2001	6.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170552 **Seq:** 1 **Gender:** M
Reported: 30/11/2001 **Weight:**
Hospitalisation: **Age:** 62
Onset Date: 13/11/2001 **DOB:** 28/02/1939
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Cardiac problems.	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 10/07/1996 **Stopped:** 13/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 13/11/01

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170553 **Seq:** 1 **Gender:** M
Reported: 30/11/2001 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 10/11/2001 **DOB:** 01/01/1970
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug) **Reason:** Depression

0.0

Batch: **Started:** **Stopped:** 10/11/2001

CLOZARIL (Suspected) **Reason:**

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 14/10/1999 **Stopped:** 10/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been chronically suicidal. patient died 10/11/01.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170616 **Seq:** 1
Reported: 30/11/2001
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

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

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Psychotic disorder Salivary hypersecretion			Patient was hospitalised and treated with amitriptyline. it was decided to gradually reduce and ceased valproate. amitriptyline was discontinued.

Medicine Details:

AMITRIPTYLINE HYDROCHLORIDE (Suspected)			**Reason:**	
	0.0			
Batch:	**Started:**			**Stopped:**
CLOZAPINE (Suspected)			**Reason:**	Schizophrenia
	300.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**
SODIUM VALPROATE (Suspected)			**Reason:**	
	800.0	Milligram	Daily	
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils				Nc 3.9 x 10?9/l, nc 1.8 x 10?9/l.
	White blood cells				Wbc 6.2 x 10?9/l, wbc 3.3 x 10?9/l.

Additional Information:

Journal: australian & new zealand journal of psychiatry author: pantelis c, adresanya a. tittle: increased risk of neutropenia and agranulocytosis with sodium valproat used adjunctively with clozapine. volume: 35 (4) year:2001 pages:544-545.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170618 **Seq:** 1
Reported: 30/11/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/11/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 34
DOB: 05/04/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Hospitalised

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet	0.0	Daily	Oral

Batch: **Started:** 08/12/1994 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was on 700mg clozaril on 24/10/01 and on 100mg on 11/11/01. the date of onset is not necessarily accurate but indicates onset sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170619 **Seq:** 1 **Gender:** F
Reported: 30/11/2001 **Weight:**
Hospitalisation: **Age:** 59
Onset Date: 28/11/2001 **DOB:** 05/01/1942
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Ceased clozaril. treated with frusemide and metoprolol.

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 03/05/2001 **Stopped:** 28/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Baseline echocardiogram normal at beginning of clozaril therapy; at 6 months a repeat echo showed mild-moderate cardiomyopathy with reduction in left ventricular function. date unknown echocardiogram (ecg) showed left bundle branch block (lbbb), repeat echocardiogram (2 months later) showed no change.

Additional Information:

The onset date is not necessarily accurate but indicates onset sometime in the month. the dose stop date is not necessarily accurate but inicates clozaril was stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170731 **Seq:** 1 **Gender:** M
Reported: 30/11/2001 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: 13/08/2001 **DOB:** 06/08/1978
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection Neutropenia		Chest infection	 Clozaril ceased.

Medicine Details:

BACTRIM (Other drug) **Reason:**
1.0 International Unit Daily
Batch: **Started:** 11/08/2001 **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 21/01/1997 **Stopped:** 15/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/01/1997	3.8X10?9/L	
	Neutrophils		13/08/2001	1.2X10?9/L	
	Neutrophils		16/08/2001	2.6X10?9/L	
	Neutrophils		15/08/2001	1.7X10?9/L	
	White blood cells		22/01/1997	5.6X10?9/L	
	White blood cells		13/08/2001	2.6X10?9/L	
	White blood cells		15/08/2001	3.3X10?9/L	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170731 **Seq:** 1 **Gender:** M
Reported: 30/11/2001 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: 13/08/2001 **DOB:** 06/08/1978
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

BACTRIM (Other drug) **Reason:**
1.0 International Unit Daily
Batch: **Started:** 11/08/2001 **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 21/01/1997 **Stopped:** 15/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		16/08/2001	3.9X10?9/L	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170769 **Seq:** 1
Reported: 05/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/11/2001
Outcome: Recovered

Gender: M
Weight: 93.00
Age: 38
DOB: 29/08/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
C-reactive protein increased			
Cardiac failure			
Dyspnoea			
Hypoxia			
Influenza like illness			
Malaise			
Myalgia			
Myocarditis			
Pain			
Pyrexia			

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug) **Reason:** Diabetes mellitus

Tablet	3.0	Gram	Daily	Oral
Batch:	**Started:**	L TERM	**Stopped:**	

PROTAPHANE (Other drug) **Reason:** Diabetes mellitus

Injection	62.0	Unit	Daily	Subcutaneous
Batch:	**Started:**	L TERM	**Stopped:**	

SODIUM VALPROATE (Other drug) **Reason:**

Oral application	1.5	Gram	Daily	Oral
Batch:	**Started:**	L TERM	**Stopped:**	

RANITIDINE (Other drug) **Reason:**

Tablet	300.0	Milligram	Daily	Oral
Batch:	**Started:**	L TERM	**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/12/2001	C-Reactive Protein				
05/12/2001	Chest X-ray				
05/12/2001	Creatine phosphokinase				
05/12/2001	Eosinophils				
05/12/2001	Erythrocyte sedimentation rate				
17/12/2002	Other data				
05/12/2001	Other data				

Additional Information:

No previous exposure to clozaril.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170769 **Seq:** 1
Reported: 05/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/11/2001
Outcome: Recovered

Gender: M
Weight: 93.00
Age: 38
DOB: 29/08/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Red blood cell sedimentation rate i Tachycardia Troponin increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 31/10/2001 **Stopped:** 19/11/2001

EPILIM (Suspected) **Reason:** Schizophrenia
250.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/12/2001	Serum drug level				

Additional Information:

No previous exposure to clozaril.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170782 **Seq:** 1
Reported: 05/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/11/2001
Outcome: Recovered

Gender: F
Weight:
Age: 46
DOB: 23/07/1955
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anorexia Dehydration Nausea Renal failure acute Vomiting			Clozaril ceased. patient hospitalised

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 05/11/2001 **Stopped:** 19/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170783 **Seq:** 1 **Gender:** F
Reported: 05/12/2001 **Weight:**
Hospitalisation: **Age:** 54
Onset Date: **DOB:** 06/08/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 06/12/1993 **Stopped:** 28/07/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170946 **Seq:** 1
Reported: 01/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/10/2001
Outcome: Recovered

Gender: M
Weight:
Age: 34
DOB: 01/07/1967
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pain Cough Diarrhoea Headache Myocarditis Pyrexia Somnolence Tachycardia		Pain in the arm.	

Medicine Details:

RISPERDAL (Other drug) **Reason:**
6.0 Milligram Daily
Batch: **Started:** 27/09/2001 **Stopped:** 15/10/2001

PROTHIADEN (Other drug) **Reason:**
25.0 Milligram Daily
Batch: **Started:** 09/08/2001 **Stopped:** 17/09/2001

CIPRAMIL (Other drug) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 14/09/2001 **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 27/09/2001 **Stopped:** 17/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg showed sinus rhythm with minor non-specific st-t wave changes.
	Haematology		17/10/2001	0.26	Troponin
	Neutrophils		17/10/2001	9.4X10?9/L	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170946 **Seq:** 1
Reported: 01/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 17/10/2001
Outcome: Recovered

Gender: M
Weight:
Age: 34
DOB: 01/07/1967
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased			Patient was hospitalised in the coronary care unit. clozaril ceased. patient was expected to undergo an echocardiogram on 19/10/2001.

Medicine Details:

RISPERDAL (Other drug) **Reason:**
6.0 Milligram Daily
Batch: **Started:** 27/09/2001 **Stopped:** 15/10/2001

PROTHIADEN (Other drug) **Reason:**
25.0 Milligram Daily
Batch: **Started:** 09/08/2001 **Stopped:** 17/09/2001

CIPRAMIL (Other drug) **Reason:**
60.0 Milligram Daily
Batch: **Started:** 14/09/2001 **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 27/09/2001 **Stopped:** 17/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Echocardiogram performed on the 19 oct 2001 demonstrated mild global reduction in lv systolic function and a small pericardial effusion. a repeat echo- cardiogram performed on the 24 oct 2001 showed cardiac function had returned to normal and effusion had resolved.
	White blood cells		17/10/2001	13.1X10?9	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 170949 **Seq:** 1 **Gender:** M
Reported: 07/12/2001 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 28/11/2001 **DOB:** 19/03/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Troponin increased			Clozaril was discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 08/11/2001 **Stopped:** 21/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin		21/11/2001	0.10	
	Troponin		23/11/2001	0.32	
	Troponin		28/11/2001	0.08	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171096 **Seq:** 1 **Gender:** M
Reported: 13/12/2001 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 22/11/2001 **DOB:** 22/11/1976
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Clozapine reduced to 650mg then to 350mg.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 17/04/2001 **Stopped:** 02/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		29/10/2001	3.5	
	White blood cells		31/10/2001	3.7	
	White blood cells		02/11/2001	3.5	
	White blood cells		05/11/2001	3.6	
	White blood cells		08/11/2001	3.7	
	White blood cells		12/11/2001	4.3	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171097 **Seq:** 1
Reported: 13/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 19/11/2001
Outcome: Unknown

Gender: M
Weight:
Age: 40
DOB: 06/04/1961
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Hepatic function abnormal Pneumonia		Tachycardia >160	Patient hospitalised.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**

Tablet 175.0 Milligram Daily Oral

Batch: **Started:** 10/10/2001 **Stopped:** 19/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171099 **Seq:** 1
Reported: 13/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 28/11/2001
Outcome: Unknown

Gender: M
Weight:
Age: 31
DOB: 18/12/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ketosis Hyperglycaemia		Diabetic ketoacidosis	Patient hospitalised, icu intubated. clozapine dose reduced, then ceased. insulin given.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 22/09/2000 **Stopped:** 27/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				Bsl of 87

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171114 **Seq:** 1 **Gender:** F
Reported: 14/12/2001 **Weight:**
Hospitalisation: **Age:** 56
Onset Date: 26/11/2001 **DOB:** 08/09/1945
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia			Clozapine ceased.

Medicine Details:

PREMIA 5 (Other drug) **Reason:** Menopausal symptoms
0.0
Batch: **Started:** **Stopped:**

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

SINUTAB (Other drug) **Reason:**
Tablet 4.0 Dose Unspecified Daily Oral
Batch: **Started:** 24/11/2001 **Stopped:** 26/11/2001

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 187.5 Milligram Daily Oral
Batch: **Started:** 12/10/2001 **Stopped:** 26/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		26/11/2001	1.6	
	White blood cells		26/11/2001	2.6	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171180 **Seq:** 1 **Gender:** M
Reported: 07/11/2001 **Weight:**
Hospitalisation: **Age:** 22
Onset Date: 16/09/2001 **DOB:** 26/07/1979
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis	Severe	Severe leukocytosis.	
Leukocytosis	Severe	Severe neutrophilia.	
Pharyngitis	Severe	Severe tonsillitis.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 750.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		16/09/2001	15.7	
	White blood cells		16/09/2001	21.2	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171388 **Seq:** 1 **Gender:** M
Reported: 18/12/2001 **Weight:** 96.00
Hospitalisation: **Age:** 27
Onset Date: 01/12/2001 **DOB:** 19/05/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Cardiac failure Dyspnoea Pulmonary hypertension		Life threatening rection	Patient hospitalised. given lasix, lisinopril, carvedilol, digoxin, warfarin.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
200.0 Milligram Daily
Batch: **Started:** **Stopped:** 07/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Echo lvef 15-20% on 10/12/01 - left ventricle is dilated and demonstrates a severe global reduction in systolic function. normal aortic valve, mild mitr al regurgitation secondary to annular dilation. moderate biatrial dilation. moderate tricuspid regurgitation with rvsp 50mmilg. moderate pulmonary hypertension at rest.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171428 **Seq:** 1 **Gender:** M
Reported: 20/12/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 29/11/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 24/11/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171431 **Seq:** 1
Reported: 20/12/2001
Hospitalisation: Admitted to hospital
Onset Date: 01/12/2001
Outcome: Recovered

Gender: F
Weight:
Age: 57
DOB: 14/02/1944
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothermia Disseminated intravascular coagul Leukocytosis Syncope Thrombocytopenia Vomiting		24 degrees celcius.	Patient was admitted to the intensive care unit. clozaril discontinued. patient treated with antibiotics and inotropes.

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** **Stopped:**

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 23/06/1995 **Stopped:** 01/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Doctor queried sepsis of unknown origin.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171457 **Seq:** 1 **Gender:** F
Reported: 02/01/2002 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 11/12/2001 **DOB:** 21/05/1944
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet	300.0 Milligram	Daily	Oral
Batch:	**Started:** 27/11/1997	**Stopped:**	28/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171582 **Seq:** 1 **Gender:** M
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Ventricular dysfunction	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** 01/01/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Echocardiography showed some left ventricular dysfunction.

Additional Information:

The dose start date is not necessarily accurate but indicates clozaril was started sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171583 **Seq:** 1 **Gender:** M
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 28/12/2001 **DOB:** 10/07/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Blood creatine phosphokinase incr Leukocytosis Pyrexia		Left ventricular dilation/systolic dysfunction	

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 01/12/2001 **Stopped:** 28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Tropin levels were negative.
	Neutrophils		26/12/2001	8.7	
	Radiololgy				The echocardiography showed left ventricular dilation.
	White blood cells		28/12/2001	12.2	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171585 **Seq:** 1 **Gender:** F
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 24/10/1957
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Reduction of clozaril dose to 400mg. treated with epilim 400mg bid.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 0.0 Oral
Batch: **Started:** 17/09/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171586 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 19/12/2001
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 47
DOB: 06/08/1954
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced Clozapine-related myocarditis, dysponea, chest pain, pyrexia, hypotension, red blood cell sedimentation rate increased, C-reactive protein increased and eosinophil count increased.	
Anorexia			
Arthralgia			
Blood creatine phosphokinase incr			
C-reactive protein increased			
Chest pain			
Dyspnoea			

Medicine Details:

MULTIVITAMINS (Other drug) **Reason:**
0.0
Batch: **Started:** 13/11/2001 **Stopped:**

DIAZEPAM (Other drug) **Reason:**
0.0 Daily
Batch: **Started:** 13/11/2001 **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 28/11/2001 **Stopped:** 28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/01/2002	C-Reactive Protein		02/09/2003	56	
07/01/2002	C-Reactive Protein		02/09/2003	-	
07/01/2002	C-Reactive Protein		02/09/2003	-	
07/01/2002	C-Reactive Protein		18/12/2001	56	
07/01/2002	C-Reactive Protein		02/09/2003	-	
07/01/2002	Creatine		02/09/2003	869	
07/01/2002	Creatine		02/09/2003	606	

Additional Information:

Clozapine dose 12.5mg/day up to 350mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171586 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 19/12/2001
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 47
DOB: 06/08/1954
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia			
Fatigue			
Influenza like illness			
Malaise			
Pyrexia			
Red blood cell sedimentation rate i			
Troponin increased			

Medicine Details:

MULTIVITAMINS (Other drug) **Reason:**
0.0
Batch: **Started:** 13/11/2001 **Stopped:**

DIAZEPAM (Other drug) **Reason:**
0.0 Daily
Batch: **Started:** 13/11/2001 **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 28/11/2001 **Stopped:** 28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/01/2002	Creatine phosphokinase		02/09/2003	243	
07/01/2002	Creatine phosphokinase		18/12/2001	869	
07/01/2002	Creatine phosphokinase		19/12/2001	606	
07/01/2002	Creatine phosphokinase		02/09/2003	48	
07/01/2002	Creatine phosphokinase		20/12/2001	243	
07/01/2002	Creatine phosphokinase		24/12/2001	48	

Additional Information:

Clozapine dose 12.5mg/day up to 350mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171586 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 19/12/2001
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 47
DOB: 06/08/1954
Causality: Causality probable

Reaction Details:

Medicine Details:

MULTIVITAMINS (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:** 13/11/2001		**Stopped:**
DIAZEPAM (Other drug)		**Reason:**	
	0.0	Daily	
Batch:	**Started:** 13/11/2001		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	
Tablet	350.0 Milligram	Daily	Oral
Batch:	**Started:** 28/11/2001		**Stopped:** 28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/01/2002	Echocardiogram				echocardiography showed normal left ventricular size, normal right ventricular size, ventricular function normal and atria not dilated.
07/01/2002	Ejection fraction				19/12/01: ejection fraction 60%
07/01/2002	Eosinophils				Eosinophils increased (0.44 to 0.69)
07/01/2002	Serum drug level				Clozapine - 740
07/01/2002	Troponin		02/09/2003	-	

Additional Information:

Clozapine dose 12.5mg/day up to 350mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171586 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 19/12/2001
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 47
DOB: 06/08/1954
Causality: Causality probable

Reaction Details:

Medicine Details:

MULTIVITAMINS (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:** 13/11/2001		**Stopped:**
DIAZEPAM (Other drug)		**Reason:**	
	0.0	Daily	
Batch:	**Started:** 13/11/2001		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	
Tablet	350.0 Milligram	Daily	Oral
Batch:	**Started:** 28/11/2001		**Stopped:** 28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/01/2002	Troponin		02/09/2003	0.6	
07/01/2002	Troponin		02/09/2003	-	
07/01/2002	Troponin		02/09/2003	-	
07/01/2002	Troponin		19/12/2001	0.6	

Additional Information:

Clozapine dose 12.5mg/day up to 350mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171587 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 04/12/2001
Outcome: Recovered

Gender: M
Weight:
Age: 33
DOB: 17/08/1968
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Somnolence		Accidental overdose 1.5gm of clozaril	Clozaril ceased. patient hospitalised.icu.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 150.0 Milligram 1 time Oral

Batch: **Started:** 19/11/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171588 **Seq:** 1 **Gender:** M
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: **DOB:** 13/08/1969
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ileus paralytic			Naso-gastric tube. clozaril reduced.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 02/11/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The reaction re-occurred on 07/12/01 and was ongoing.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171589 **Seq:** 1 **Gender:** M
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:** 56
Onset Date: 01/12/2001 **DOB:** 10/11/1945
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anorexia			
Atrial fibrillation			
Diabetes mellitus			
Hypertension			
Myocarditis			Patient hospitalised. icu admission for 1 week.
Pneumonia			
Renal impairment			

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 09/11/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest x-ray showed cardiomegaly and pulmonary venous congestion consistent with cardiac failure. the lungs were poorly aerated. there was confluent opacity in the left lower zone obscuring the left hemidiaphragm consistent with left basal collapse/consolidation.
	Electrocardiograph				Electrocardiogram showed atrial fibrillation

Additional Information:

Patient history: smoker, obesity, hypertension, diabetes mellitus, hypercholesterolaemia.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171590 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/12/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 54
DOB: 14/03/1947
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation Myocarditis			Patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 175.0 Milligram Daily Oral

Batch: **Started:** 13/11/2001 **Stopped:** 07/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171591 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/12/2001
Outcome: Recovered

Gender: M
Weight:
Age: 29
DOB: 31/03/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	400.0 Milligram	Daily	Oral	
Batch:	**Started:** 19/04/2001		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Excessive drinking of water wich lead to decreased sodium levels.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171592 **Seq:** 1 **Gender:** F
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 28/12/1999 **DOB:** 08/01/1967
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			Control the patient's diet. reaction resolving.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 02/12/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171593 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 10/12/2001
Outcome: Recovered

Gender: F
Weight:
Age: 27
DOB: 25/09/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Ketosis Weight increased			Patient hospitalised. patient will discontinue clozaril.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 01/12/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171600 **Seq:** 1 **Gender:** M
Reported: 04/01/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 27/12/2001 **DOB:** 20/05/1961
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neoplasm malignant			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 17/08/1998 **Stopped:** 27/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of death: 27/12/2001.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171637 **Seq:** 1 **Gender:** U
Reported: 02/01/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 13/12/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Myocardial infarction Myocarditis Pyrexia Troponin increased			Patient hospitalsied.

Medicine Details:

OLANZAPINE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
MODECATE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	Unspecified schizophrenia
Tablet	0.0		Oral
Batch:	**Started:** 01/11/2001		**Stopped:** 13/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase				Cpk level was raised to 3000 and troponin level was also raised.
	Other data	`			Echocardiogram indicated myocarditis.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171638 **Seq:** 1
Reported: 02/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 26/08/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 58
DOB: 13/06/1943
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Lymphocytosis Multiple myeloma Neutropenia			Patient hospitalised. chemotherapy given. treated with g-csf.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 06/12/1994 **Stopped:** 31/05/2001

CLOZARIL (Suspected) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 01/07/2001 **Stopped:** 04/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils	2.00 - 7.50	26/08/2001	0.77	
	Neutrophils	2.00 - 7.50	28/08/2001	1.21	
	Neutrophils	2.00 - 7.50	24/01/2002	1.63	
	Neutrophils	2.00 - 7.50	14/02/2002	5.20	
	Neutrophils	2.00 - 7.50	04/02/2002	0.27	
	White blood cells	4.00 - 11.00	26/08/2001	1.70	
	White blood cells	4.00 - 11.00	28/08/2001	2.50	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171638 **Seq:** 1
Reported: 02/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 26/08/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 58
DOB: 13/06/1943
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	600.0 Milligram		Daily	Oral
Batch:	**Started:** 06/12/1994		**Stopped:** 31/05/2001	
CLOZARIL (Suspected)			**Reason:**	
Tablet	450.0 Milligram		Daily	Oral
Batch:	**Started:** 01/07/2001		**Stopped:** 04/02/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells	4.00 - 11.00	24/01/2002	2.9	
	White blood cells	4.00 - 11.00	04/02/2002	1.2	
	White blood cells	4.00 - 11.00	14/02/2002	6.33	

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171703 **Seq:** 1 **Gender:** F
Reported: 02/01/2002 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 30/11/2001 **DOB:** 04/01/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Abdominal pain Diarrhoea Nausea Somnolence Tachycardia Vomiting		Body temperature increased.	

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 1.2 Gram Daily Oral
Batch: **Started:** 29/08/2001 **Stopped:** 03/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171705 **Seq:** 1 **Gender:** F
Reported: 02/01/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 02/06/1952
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Pronounced, prolonged stammer.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 22/03/1995 **Stopped:** 20/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous history of stuttering; history of long-standing schizophrenia, for which patitent had received electro-convulsive therapy in the past.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171723 **Seq:** 1
Reported: 02/01/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 54
DOB: 28/01/1947
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia Leukocytosis Respiratory failure		Infective exacerbation of coad, death.	Patient was hospitalised. patient died 27 months after commencing clozaril.

Medicine Details:

SPAN-K (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

ATROVENT (Other drug) **Reason:**
0.5 Millilitre Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 14/07/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Severe chronic obstructive airways disease (coad), type ii chronic respiratory failure, obstructive sleep apnea (osa).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171769 **Seq:** 1 **Gender:** F
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 18/12/2001 **DOB:** 18/08/1977
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Pallor Somnolence			Patient hospitalised. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 18/12/2001 **Stopped:** 18/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171789 **Seq:** 1 **Gender:** M
Reported: 09/01/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 27/12/2001 **DOB:** 20/01/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 20/12/2001 **Stopped:** 28/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		27/12/2001	740	
	AST = SGOT		27/12/2001	341	
	GGT = SGGT = [illegible]		27/12/2001	152	
	LDH		27/12/2001	424	
	SAP = ALP		27/12/2001	123	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171790 **Seq:** 1
Reported: 09/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 27/12/2001
Outcome: Unknown

Gender: M
Weight:
Age: 21
DOB: 11/06/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Psychotic disorder			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	300.0 Milligram	Daily	Oral	
Batch:	**Started:** 07/09/2001		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

There was a possibility that the patient had stopped taking clozaril for 2 days.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171865 **Seq:** 1 **Gender:** M
Reported: 02/01/2002 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 08/08/2001 **DOB:** 22/12/1976
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			Clozaril dose was reduced to 75mg as treatment.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 07/07/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				Blood sugar leve was 53mmol/dl.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171890 **Seq:** 1
Reported: 07/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 08/12/2001
Outcome: Recovered

Gender: M
Weight:
Age: 40
DOB: 17/01/1961
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Deterioration of self care	Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 900.0 Milligram Daily Oral

Batch: **Started:** 22/01/1993 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 171992 **Seq:** 1 **Gender:** F
Reported: 18/01/2002 **Weight:** 110.00
Hospitalisation: **Age:** 59
Onset Date: 05/10/2001 **DOB:** 05/01/1942
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bundle branch block Cardiomyopathy		Left bundle branch block	 Ceased clozapine.

Medicine Details:

SODIUM VALPROATE (Suspected)			**Reason:**	
Tablet	0.0			Oral
Batch:	**Started:** 01/09/2000		**Stopped:**	CONTIN
CLOZAPINE (Suspected)			**Reason:**	Schizophrenia
Tablet	200.0 Milligram	Daily		Oral
Batch:	**Started:** 01/04/2000		**Stopped:**	28/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph Other data				Lbbb noted on ecg. Routine echocardogram performed 6 months after starting clozapine showed change in systolic function.

Additional Information:

The dose start and stop date is not necessarily accurate but indicates clozapine was started and stopped sometime in the month. the dose start date is not necessarily accurate but indciate sodium valproate was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172008 **Seq:** 1 **Gender:** M
Reported: 21/01/2002 **Weight:**
Hospitalisation: **Age:** 77
Onset Date: 28/09/2001 **DOB:** 31/08/1924
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma			Clozaril was discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 05/10/1999 **Stopped:** 05/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172012 **Seq:** 1 **Gender:** F
Reported: 20/12/2001 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: **DOB:** 04/07/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intra-uterine death		Abortion spontaneous	Patient discontinued clozaril on 6/11/01 when she became prgnant.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 27/06/2001 **Stopped:** 06/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172032 **Seq:** 1 **Gender:** F
Reported: 21/01/2002 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Neutropenia			Gradually reduce and cease sodium valproate. amitriptyline discontinued.

Medicine Details:

CLOPINE (Interaction)			**Reason:**	Unspecified schizophrenia	
Tablet	600.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
SODIUM VALPROATE (Interaction)			**Reason:**	Unspecified schizophrenia	
Oral application	800.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
AMITRIPTYLINE HYDROCHLORIDE (Other drug)			**Reason:**	Salivary secretion disturbance	
Tablet	25.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils				Neutrophil count dropped from an average 3.9x10?9/l in the 6 weeks prior to commencing sodium valproate, to 1.8x10?9/l.
	White blood cells				White cell count dropped from an average of 6.2x10?9/l in the 6 weeks prior to commencing sodium valproate, to 3.3x10?9/l.

Additional Information:

Patient suffered several relapses of her illness requiring hospitalisation. increased risk of neutropenia and agranulocytosis with sodium valproate used adjunctively with clozapine, christos pantelis and adesina adesanya aust nz journal of psychiatry 2001, 35(4), p 544.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172127 **Seq:** 1
Reported: 09/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 08/11/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 36
DOB: 22/08/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Chest pain Electrocardiogram T wave inversio Somnolence Tachycardia		Intermittent chest pain.	Patient was hospitalised. clozaril reduced and cipramil changed to zoloft. treated with atenolol.

Medicine Details:

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

BENZTROPINE MESYLATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 31/10/2001 **Stopped:** 20/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				T wave inversion of v4-6 on ecg.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172127 **Seq:** 1
Reported: 09/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 08/11/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 36
DOB: 22/08/1965
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia	
Tablet	300.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172192 **Seq:** 1
Reported: 25/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 31
DOB: 10/10/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Somnolence Therapeutic response increased			Treated with risperidone 1mg daily, intubated and ventilation. clozaril ceased.

Medicine Details:

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

CLOZARIL (Interaction) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 15/06/1999 **Stopped:** 06/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172193 **Seq:** 1
Reported: 25/01/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 27
DOB: 19/05/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Cardiomyopathy Dizziness Dyspnoea Fatigue Tachycardia			Patient was hospitalised. stabilised with lasix, lisinopril, carvedilol, digoxin, warfarin and ventolin.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 27/06/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Echocardiogram showed left ventricle dilated and demonstrated a severe global reduction in systolic function, left ventricle ejection fraction 15-20%, normal aortic valve, mild mitral regurgitation secondary to annular dilatation. moderate biatrial dilatation, moderate tricuspid regurgitation with right ventricle sinus pressure 50mmhg.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172194 **Seq:** 1 **Gender:** F
Reported: 25/01/2002 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 06/08/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure			Clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 25/10/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph Radiololgy				Ecg and lab data showed no abnormalities. Ejection fraction of 24% on echocardiography.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172197 **Seq:** 1 **Gender:** U
Reported: 25/01/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Malignant melanoma		Melanoma on the groin.	Treated with radiotherapy. patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172223 **Seq:** 1 **Gender:** M
Reported: 29/01/2002 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 25/11/2001 **DOB:** 01/03/1968
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Drug ineffective		Completed suicide.	

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia

Tablet 650.0 Milligram Daily Oral

Batch: **Started:** 20/09/2001 **Stopped:** 25/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172234 **Seq:** 1 **Gender:** M
Reported: 25/01/2002 **Weight:** 101.00
Hospitalisation: **Age:** 25
Onset Date: 19/10/2001 **DOB:** 14/10/1976
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations Tachycardia			Clozaril discontinued.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 125.0 Milligram Daily Oral
Batch: **Started:** 19/01/1996 **Stopped:** 04/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Echocardiography which resulted in no abnormalities.

Additional Information:

Echocardiography which resulted in no abnormalites.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172249 **Seq:** 1 **Gender:** F
Reported: 25/01/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 28/12/2001 **DOB:** 19/01/1952
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma Confusional state Hyperglycaemia Hyperlipidaemia			Lithium ceased, clozaril reduced.

Medicine Details:

LITHIUM CARBONATE (Interaction) **Reason:**
Oral application 0.0 Oral
Batch: **Started:** 01/12/2001 **Stopped:** CONTIN

CLOZARIL (Interaction) **Reason:** Unspecified schizophrenia
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 26/10/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				The blood glucose level=9. the result of the last clozaril level taken in july 2001 was 593ng/ml. the patient's blood lipids were also slightly elevated.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172263 **Seq:** 1 **Gender:** M
Reported: 29/01/2002 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 11/01/2002 **DOB:** 17/07/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder Myocarditis		Cardiac complications	Patient has been referred to a cardiologist. clozapine was ceased.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 24/12/2001 **Stopped:** 10/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172343 **Seq:** 1 **Gender:** M
Reported: 01/02/2002 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 27/11/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder			

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 28/12/2001 **Stopped:** 18/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Troponin levels had increased on day 19.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172357 **Seq:** 1
Reported: 04/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 22/01/2002
Outcome: Recovered

Gender: F
Weight:
Age: 23
DOB: 12/09/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			Clozaril discontinued. patient hospitalised

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 10/09/1999 **Stopped:** 27/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/01/2002	1.76	
	Neutrophils		23/01/2002	1.49	
	Neutrophils		24/01/2002	1.35	
	White blood cells		22/01/2002	2.98	
	White blood cells		23/01/2002	3.10	
	White blood cells		24/01/2002	2.93	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172358 **Seq:** 1
Reported: 04/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 17/01/2002
Outcome: Unknown

Gender: M
Weight:
Age: 32
DOB: 26/11/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 175.0 Milligram Daily Oral

Batch: **Started:** 05/01/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172362 **Seq:** 1 **Gender:** F
Reported: 04/02/2002 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 15/01/2002 **DOB:** 25/06/1964
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 800.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin		15/01/2002	9.4	
	Troponin		16/01/2002	8.3	
	Troponin		17/01/2002	7.7	
	Troponin		18/01/2002	9.9	
	Troponin		19/02/2002	1.2	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172363 **Seq:** 1 **Gender:** M
Reported: 04/02/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 31/12/2001 **DOB:** 26/09/1980
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Treated by increasing the dose of eplim.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 01/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient quit smoking in oct 2001. the patient also experienced heart palpitations in 2000. the dose start date is not necessarily accurate but indicates clozaril was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172364 **Seq:** 1
Reported: 04/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 21
DOB: 10/03/1980
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged Orthostatic hypotension			Clozaril reduced.

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 16/05/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Borderline to high qt interval on the electrocardiogram (ecg). follow-up ecg was unremarkable.

Additional Information:

Relevant history - tachycardia nos. the date of onset is not necessarily accurate but indicates onset sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172398 **Seq:** 1 **Gender:** F
Reported: 04/02/2002 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 07/01/2002 **DOB:** 05/12/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia Leukocytosis Leukocytosis			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 23/11/1999 **Stopped:** 14/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172399 **Seq:** 1 **Gender:** M
Reported: 04/02/2002 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 31/12/2000 **DOB:** 26/09/1980
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations			Reduced the dose of clozaril.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				An echocardiogram (echo) was performed and no abnormalities were detected.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172440 **Seq:** 1
Reported: 06/02/2002
Hospitalisation: Treated in outpatient department only.
Onset Date: 27/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 31
DOB: 03/11/1970
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Hypertension Leukocytosis Tachycardia			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 20/01/2002 **Stopped:** 29/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				25/1/02: blood pressure = 169/99mmhg.
	Neutrophils		25/01/2002	8.7	
	White blood cells		25/01/2002	13.4	

Additional Information:

Family history of seizures.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172441 **Seq:** 1
Reported: 06/02/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight:
Age: 47
DOB: 17/04/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Uncontrolled seizures for 20 min.	Patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 800.0 Milligram Daily Oral

Batch: **Started:** 01/02/2000 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172485 **Seq:** 1 **Gender:** F
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 05/12/2001 **DOB:** 07/06/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bundle branch block			
Dyspnoea			
Eosinophilia			
Influenza like illness			
Myocarditis			
Pyrexia			
Tachycardia			

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.6 Gram Daily
Batch: **Started:** **Stopped:** CONTIN

CELEBREX (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
200.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

CLONAZEPAM (Other drug) **Reason:** Otr spec symp psychopathol nec
Oral application 0.5 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 02/11/2001 **Stopped:** 05/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils		06/12/2001	0.48	
	Eosinophils		08/12/2001	0.4	
	Eosinophils		09/12/2001	0.63	
	Eosinophils		10/12/2001	0.7	
	Radiololgy				Echocardiography showed mild pericardial effusion
	Troponin		05/12/2001	0.8	
	White blood cells		06/12/2001	9.5	

Additional Information:

Past history of chest pain and widened qrs. heavy alcohol intake. heavy smoker.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172485 **Seq:** 1 **Gender:** F
Reported: 07/01/2002 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 05/12/2001 **DOB:** 07/06/1962
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.6 Gram Daily
Batch: **Started:** **Stopped:** CONTIN

CELEBREX (Other drug) **Reason:** Otr&unsp vertebrogen pain synd
200.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:** CONTIN

CLONAZEPAM (Other drug) **Reason:** Otr spec symp psychopathol nec
Oral application 0.5 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 02/11/2001 **Stopped:** 05/12/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		08/12/2001	9.6	
	White blood cells		09/12/2001	-	
	White blood cells		10/12/2001	11.9	
	White blood cells		13/12/2001	11.2	
	White blood cells		20/12/2001	11.80	

Additional Information:

Past history of chest pain and widened qrs. heavy alcohol intake. heavy smoker.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172487 **Seq:** 1
Reported: 09/01/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/07/2001
Outcome: Not yet recovered

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

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			Patient hospitalised. treated with insulin. clozaril was eventually ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 0.0 Oral

Batch: **Started:** 01/07/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Strong family history of diabetes. the date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date for clozaril is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172621 **Seq:** 1 **Gender:** F
Reported: 11/02/2002 **Weight:**
Hospitalisation: **Age:** 67
Onset Date: 22/11/2001 **DOB:** 26/06/1934
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aspiration Cardio-respiratory arrest Hyponatraemia Intestinal obstruction Vomiting			Date of death 24.11.01.

Medicine Details:

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

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

QUININE SULPHATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Abdomen X-ray				22/11/01: x-ray revealed grossly distended bowel, distended abdomen, but gas and faeces in rectum.
	Creatinine	0.05 - 0.10	22/11/2001	0.34	
	Sodium		22/11/2001	111	
	Urea	3.0 - 8.0	22/11/2001	16.6	

Additional Information:

Patient experienced faecal impaction and vomiting with aspiration causing cardio-respiratory arrest.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172621 **Seq:** 1
Reported: 11/02/2002
Hospitalisation:
Onset Date: 22/11/2001
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 67
DOB: 26/06/1934
Causality: Causality possible

Reaction Details:

Medicine Details:

OESTROGENS NOS (Other drug)		**Reason:**	
Ointment	0.0		Topical
Batch:	**Started:**		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	Unspecified schizophrenia
Tablet	400.0 Milligram	Daily	Oral
Batch:	**Started:** 15/01/1997		**Stopped:**

Laboratory Investigations:

Additional Information:

Patient experienced faecal impaction and vomiting with aspiration causing cardio-respiratory arrest.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172708 **Seq:** 1 **Gender:** F
Reported: 14/02/2002 **Weight:** 75.00
Hospitalisation: **Age:** 22
Onset Date: 30/01/2002 **DOB:** 23/05/1979
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia			Sodium valproate ceased. required a visit to doctor.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
300.0 Milligram Daily
Batch: **Started:** 01/11/2001 **Stopped:** CONTIN

SODIUM VALPROATE (Suspected) **Reason:**
2.0 Gram Daily
Batch: **Started:** 12/09/2001 **Stopped:** 05/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172846 **Seq:** 1
Reported: 18/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 21/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 54
DOB: 27/03/1947
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope			Patient hospitalised for 3 days.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 200.0 Milligram 1 time Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This patient accidentally took 2 tab of clozaril on 21/01/02. after 1 hour he collapsed. the patient's doughter was taking clozaril, when he mistook the tablets for paracetamol.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172847 **Seq:** 1
Reported: 18/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 21/01/2002
Outcome: Recovered

Gender: F
Weight:
Age: 53
DOB: 31/10/1948
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state			Patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 100.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient mistakenly took clozaril 100mg tablet instead of paracetamol.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172854 **Seq:** 1 **Gender:** F
Reported: 13/02/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 02/02/2002 **DOB:** 12/06/1952
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pustular		Red pustular rash on arms and legs.	Required a visit to doctor. date of recovery 6.2.02.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
200.0 Milligram Daily
Batch: **Started:** 17/01/2002 **Stopped:** 04/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172894 **Seq:** 1 **Gender:** M
Reported: 18/02/2002 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 28/10/2001 **DOB:** 15/04/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Tachycardia			Clozaril stopped. treated with seroquel and zuclopenthixol depot inj.

Medicine Details:

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

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

ZUCLOPENTHIXOL ACETATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 23/05/1999 **Stopped:** 17/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Heart rate was 110-120 beats per minute.

Additional Information:

The dose stop date is not necessarily accurate but indicates clozaril was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172945 **Seq:** 1
Reported: 21/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/01/2002
Outcome: Recovered

Gender: F
Weight: 52.00
Age: 22
DOB: 07/10/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Suspected myocarditis.	Pateint was hospitalised and treated with risperidone, will be under cardiac monitoring and weekly blood monitoring. clozaril was discontinued.
Dizziness			
Fatigue			
Malaise			
Orthostatic hypotension			
Pyrexia			
Troponin increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet	300.0 Milligram	Daily	Oral
Batch:	**Started:** 07/01/2002	**Stopped:**	28/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	C-Reactive Protein	<10	28/12/2001	-	
	C-Reactive Protein	<10	29/01/2002	71	
	Electrocardiograph				30/1/02: electrocardiogram consistent with mild left ventricle systolic dysfunction, mild mild mr.
	Eosinophils	<0.44	28/12/2001	0.6	
	Eosinophils	<0.44	29/01/2002	0.6	
	Erythrocyte	3 - 9	28/12/2001	-	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 172945 **Seq:** 1
Reported: 21/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/01/2002
Outcome: Recovered

Gender: F
Weight: 52.00
Age: 22
DOB: 07/10/1979
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 07/01/2002 **Stopped:** 28/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Erythrocyte	3 - 9	29/01/2002	19	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173002 **Seq:** 1 **Gender:** M
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 23/01/2002 **DOB:** 23/09/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia Diabetes mellitus Weight increased		Asymptomatic hyperglycaemia	Treated with exercise and diet changes.

Medicine Details:

ATENOLOL (Other drug) **Reason:**
0.0
Batch: **Started:** 14/12/1999 **Stopped:** CONTIN

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
400.0 Milligram Daily
Batch: **Started:** 23/04/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data		16/05/2001	112.6KG	Weight (persistent gain)
	Other data		17/04/2002	130.5KG	Weight (persistent gain)
	Serum glucose		28/11/2001	6.9	Fasting glucose
	Serum glucose		12/12/2001	7.7	Fasting glucose
	Serum glucose		23/01/2002	7.7	Fasting glucose
	Serum glucose		17/04/2002	7.2	Fasting glucose

Additional Information:

No family history of diabetes.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173003 **Seq:** 1 **Gender:** M
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 10/10/2001 **DOB:** 16/12/1948
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia Weight increased			Amaryl and specific diet.

Medicine Details:

RANITIDINE (Other drug) **Reason:**
0.0
Batch: **Started:** 01/05/1999 **Stopped:** CONTIN

ENALAPRIL MALEATE (Other drug) **Reason:**
0.0
Batch: **Started:** 09/04/1998 **Stopped:** CONTIN

IMIPRAMINE HYDROCHLORIDE (Other drug) **Reason:**
0.0
Batch: **Started:** 01/02/2001 **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 08/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				Random blood sugar level - 13.0 mmol/l. 18/10/02 - fasting blood glucose = 9.1 and 2 hours post prandial glucose = 19.0

Additional Information:

Patient had been diabetic for 12 months at the time of reporting.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173004 **Seq:** 1 **Gender:** F
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: **DOB:** 24/05/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypercalcaemia			

Medicine Details:

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

LITHIUM CARBONATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
500.0 Milligram Daily
Batch: **Started:** 03/12/1993 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173006 **Seq:** 1 **Gender:** M
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: 24/01/2002 **DOB:** 22/12/1966
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope Somnolence Weight increased		10 blackouts lasting a few seconds each.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 450.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173074 **Seq:** 1 **Gender:** M
Reported: 25/02/2002 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 20/03/1971
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastrooesophageal reflux disease Vomiting			Cisapride and omeprazole. clozaril stopped.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 600.0 Milligram Fortnightly Oral

Batch: **Started:** 01/11/1994 **Stopped:** 28/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173119 **Seq:** 1 **Gender:** M
Reported: 25/02/2002 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: **DOB:** 16/02/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy Dyspnoea			Clozaril discontinued.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 173120 **Seq:** 1
Reported: 25/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 36
DOB: 11/06/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness	Life threatening	Life threatening.	
Fatigue	Life threatening	Life threatening.	
Hypotension	Life threatening	Life threatening.	
Malaise	Life threatening	Life threatening.	
Myalgia	Life threatening	Life threatening.	
Tachycardia	Life threatening	Life threatening.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 15/01/2002 **Stopped:** 01/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine kinase MB		31/01/2002	<3	
	Creatine phosphokinase		31/01/2002	253	
	Creatine phosphokinase		04/02/2002	57	
	Eosinophils		14/01/2002	0.22	
	Eosinophils		31/01/2002	0.21	
	Eosinophils		02/02/2002	0.32	
	Eosinophils		04/02/2002	0.35	

Additional Information:

Possible col-existent chest infection. current condition - lower respiratory tract infection nos. smoker - 30 cigarettes per day for 20 year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173120 **Seq:** 1
Reported: 25/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 36
DOB: 11/06/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Required Specialist Consultation	Mild myocarditis.	Admitted to hospital. given paracetamol. clozaril discontinued.
Pyrexia	Life threatening	Temperature greater than 39 c	
Headache			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 15/01/2002 **Stopped:** 01/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				The patient had echocardiogram abnormalities on an unknown date.
	Radiololgy				1/2/02: echocardiography showed mild global reduction in the left ventricular function and mild initial regurgitation.
	Troponin		31/01/2002	0.1	
	Troponin		02/02/2002	0.06	
	Troponin		04/02/2002	<0.01	

Additional Information:

Possible col-existent chest infection. current condition - lower respiratory tract infection nos. smoker - 30 cigarettes per day for 20 year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173120 **Seq:** 1
Reported: 25/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 36
DOB: 11/06/1965
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 15/01/2002 **Stopped:** 01/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		14/01/2002	-	
	White blood cells		31/01/2002	11.3	
	White blood cells		02/02/2002	9.5	
	White blood cells		04/02/2002	11.0	

Additional Information:

Possible col-existent chest infection. current condition - lower respiratory tract infection nos. smoker - 30 cigarettes per day for 20 year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173121 **Seq:** 1
Reported: 25/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 07/02/2002
Outcome: Recovered

Gender: M
Weight:
Age: 28
DOB: 19/12/1973
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence			Patient hospitalised overnight. given iv hydration.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 375.0 Milligram Daily Oral
Batch: **Started:** 03/12/2001 **Stopped:** 04/02/2002

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 07/02/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173122 **Seq:** 1 **Gender:** M
Reported: 25/02/2002 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 29/09/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 01/04/2001 **Stopped:** 28/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Symptoms of myocarditis on echocardiogram.

Additional Information:

Current condition - echocardiogram abnormal nos.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173123 **Seq:** 1
Reported: 25/02/2002
Hospitalisation: Admitted to hospital
Onset Date: 07/02/2002
Outcome: Recovered

Gender: M
Weight:
Age: 44
DOB: 09/09/1957
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Psychotic disorder			Patient hospitalised.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 01/01/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not accurate but indicates the drug was started sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173125 **Seq:** 1 **Gender:** F
Reported: 25/02/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 28/01/2001 **DOB:** 09/08/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Sexual intercourse without consent, heavy sedation	

Medicine Details:

SODIUM VALPROATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 03/09/1996 **Stopped:**

ALCOHOL (Suspected) **Reason:**
Oral application 1.5 Litre Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. "reaction to clozapine considered unlikely because of 5 years exposure to the drug. alcohol ingestion is a more likely explanation".

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173241 **Seq:** 1 **Gender:** M
Reported: 28/02/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 12/02/2002 **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

COGENTIN (Other drug)			**Reason:**		
Tablet	2.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
IMIPRAMINE HYDROCHLORIDE (Other drug)			**Reason:**		
Tablet	25.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia	
Tablet	450.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data	150-500UG/L			The clozaril plasma level was 1900ug/l.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173242 **Seq:** 1 **Gender:** M
Reported: 28/02/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 15/05/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Electrolyte imbalance			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** **Stopped:** 09/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Creatine kinase (ck) at 59,000.

Additional Information:

Patient history: patient is a heavy drinker and possibly using drugs.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173243 **Seq:** 1 **Gender:** F
Reported: 28/02/2002 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: 15/02/2002 **DOB:** 02/02/1972
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics	0.45-1.5.			22/1/02: clozapine level = 4.7 13/2/02: clozapine level = 3.4

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173339 **Seq:** 1
Reported: 28/02/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Death

Gender: M
Weight: 0.00
Age: 60
DOB: 27/07/1941
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 29/12/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/02/2002	Autopsy report				Pneumonia involving both lungs. This condition directly caused his death.
16/12/2002	Serum drug level				14/12/01: clozapine lever = 0.62 and norclozapine = 0.83

Additional Information:

Other secondary diagnoses were bilateral artery stenosis, chronic obstructive airway disease, hypercholesterolaemia, hypertriglyceridaemia and peripheral neuropathy. patient smoked 40 cigarettes per day and quit in march 2001. patient had been diagnosed in the past with hypertension, diabetes mellitus, right bell's palsy, excess alcohol intake in the past, mild cerebral atrophy. reaction occurred sometime in december 2001.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173351 **Seq:** 1 **Gender:** M
Reported: 05/03/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 28/11/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Medication error Somnolence		Accidental administration of higher dose.	Patient was hospitalised for observation. clozaril was withheld temporarily.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 475.0 Milligram 1 time Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was accidentally administered a higher dose (475mg rather than 125mg which he was originally prescribed).

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173386 **Seq:** 1 **Gender:** F
Reported: 05/03/2002 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 19/02/2002 **DOB:** 20/03/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Leukopenia Neutropenia			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 23/10/2001 **Stopped:** 19/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		18/10/2001	3.11	
	Neutrophils		11/02/2002	2.24	
	Neutrophils		19/02/2002	0.44	
	Neutrophils		18/02/2002	0.64	
	Neutrophils		23/02/2002	0.45	
	Neutrophils		04/03/2002	2.13	
	Neutrophils		25/02/2002	0.52	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173386 **Seq:** 1 **Gender:** F
Reported: 05/03/2002 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 19/02/2002 **DOB:** 20/03/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 23/10/2001 **Stopped:** 19/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		21/02/2002	0.74	
	Neutrophils		20/02/2002	0.57	
	White blood cells		18/10/2001	5.70	
	White blood cells		11/02/2002	4.10	
	White blood cells		18/02/2002	1.70	
	White blood cells		19/02/2002	1.70	
	White blood cells		20/02/2002	2.00	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173386 **Seq:** 1 **Gender:** F
Reported: 05/03/2002 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 19/02/2002 **DOB:** 20/03/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 350.0 Milligram Daily Oral
Batch: **Started:** 23/10/2001 **Stopped:** 19/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		21/02/2002	2.10	
	White blood cells		23/02/2002	1.9	
	White blood cells		25/02/2002	1.9	
	White blood cells		04/03/2002	4.40	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173413 **Seq:** 1
Reported: 07/03/2002
Hospitalisation:
Onset Date: 11/02/2002
Outcome: Not yet recovered

Gender: M
Weight: 93.00
Age: 19
DOB: 21/06/1982
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness			Required a visit to doctor.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Schizophrenia
400.0 Milligram Daily
Batch: **Started:** 01/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest x-ray showed prneomonitis type picture in midzone right lung.
	Eosinophils				Eosinophils 2.5

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173433 **Seq:** 1 **Gender:** M
Reported: 07/03/2002 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 28/11/2001 **DOB:** 31/08/1965
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia Gastrointestinal disorder			Domperidone, omeprazole.

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 14/06/2001 **Stopped:** CONTIN

PAROXETINE HYDROCHLORIDE (Suspected) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** 20/11/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Barium swallow suggests impaired oesophageal motility.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173434 **Seq:** 1
Reported: 06/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 23/02/2002
Outcome: Recovered

Gender: M
Weight:
Age: 24
DOB: 02/07/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Temp 39.5?c.	Patient hospitalised. reduce the clozaril dose to 150mg daily.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 22/01/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173435 **Seq:** 1 **Gender:** M
Reported: 05/03/2002 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 28/02/2002 **DOB:** 24/08/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bacterial infection		Septic appendix	Clozaril dose reduced. patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 750.0 Milligram Daily Oral
Batch: **Started:** 17/07/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173436 **Seq:** 1 **Gender:** M
Reported: 05/03/2002 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 15/04/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Rash erythematous Salivary gland enlargement Salivary hypersecretion Vomiting			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 625.0 Milligram Daily Oral

Batch: **Started:** 01/02/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173562 **Seq:** 1 **Gender:** M
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 19/02/2002 **DOB:** 27/05/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

AMOXYCILLIN SODIUM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 15/01/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	5 - 40	05/02/2002	198	
	ALT = SGPT	5 - 40	12/02/2002	381	
	ALT = SGPT	5 - 40	19/02/2002	1050	
	ALT = SGPT	5 - 40	26/02/2002	457	
	AST = SGOT	5 - 40	05/02/2002	80	
	AST = SGOT	5 - 40	12/02/2002	154	
	AST = SGOT	5 - 40	19/02/2002	431	

Additional Information:

The patient was found to have hepatitis c.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173562 **Seq:** 1 **Gender:** M
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 19/02/2002 **DOB:** 27/05/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

AMOXYCILLIN SODIUM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 15/01/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	5 - 40	26/02/2002	150	
	GGT = SGGT =	5 - 65	05/02/2002	-	
	GGT = SGGT =	5 - 65	12/02/2002	-	
	GGT = SGGT =	5 - 65	26/02/2002	159	
	GGT = SGGT =	5 - 65	19/02/2002	127	
	LDH	100 - 225	05/02/2002	-	
	LDH	100 - 225	02/02/2002	-	

Additional Information:

The patient was found to have hepatitis c.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173562 **Seq:** 1 **Gender:** M
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 19/02/2002 **DOB:** 27/05/1963
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

AMOXYCILLIN SODIUM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 15/01/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	LDH	100 - 225	26/02/2002	-	
	LDH	100 - 225	19/02/2002	305	
	SAP = ALP		05/02/2002	-	
	SAP = ALP		12/02/2002	-	
	SAP = ALP		19/02/2002	83	
	SAP = ALP		26/02/2002	-	

Additional Information:

The patient was found to have hepatitis c.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173563 **Seq:** 1 **Gender:** M
Reported: 11/03/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: **DOB:** 15/05/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 27/09/1996 **Stopped:** 12/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This patient was considered acutely medically unwell, approx, 5 years and 5 mo nths after commencing clozaril. the measure taken to treat the reaction was to discontinue clozaril. the reporter then indicated that the "medically unwell" referred to possible neuroleptic malignant syndrome. the patient was also non- compliant with their clozaril therapy. the reporter indicated that the patient may not be "fit"to commence clozaril again.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173586 **Seq:** 1 **Gender:** M
Reported: 13/03/2002 **Weight:** 0.00
Hospitalisation: **Age:** 26
Onset Date: 22/02/2002 **DOB:** 03/09/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly Pneumonia			

Medicine Details:

CLOMIPRAMINE HYDROCHLORIDE (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

HALOPERIDOL (Other drug) **Reason:**
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 550.0 Milligram Daily Oral
Batch: **Started:** 08/03/1994 **Stopped:** 22/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
13/03/2002	Echocardiogram				

Additional Information:

Family history - Cardiomyopathy nos (father)

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173587 **Seq:** 1 **Gender:** U
Reported: 13/03/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Multiple myeloma			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173668 **Seq:** 1 **Gender:** U
Reported: 15/03/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 04/02/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation Pneumonia Rash maculo-papular			Patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173669 **Seq:** 1 **Gender:** M
Reported: 15/03/2002 **Weight:** 93.00
Hospitalisation: **Age:** 42
Onset Date: 28/05/2001 **DOB:** 22/07/1958
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Hyperglycaemia Urinary tract infection			Antibiotics.

Medicine Details:

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

VIOXX (Other drug) **Reason:**
0.0
Batch: **Started:** 20/02/2001 **Stopped:**

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

CLOZARIL (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This patient experienced diabetes in july 2001, 8-9 years after commencing clo zaril. the diabetes was diet controlled. the patient had recently experienced a uti and was treated with antibiotics. the onset date is not necessarily accurate but indicates onset sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173680 **Seq:** 1 **Gender:** F
Reported: 15/03/2002 **Weight:** 0.00
Hospitalisation: **Age:** 54
Onset Date: 28/02/2002 **DOB:** 31/05/1947
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
750.0 Milligram Daily
Batch: **Started:** L TERM **Stopped:**

HALOPERIDOL (Other drug) **Reason:**
2.5 Milligram Daily
Batch: **Started:** **Stopped:**

PULMICORT (Other drug) **Reason:**
400.0 Microgram Daily
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/03/2002	Autopsy report				1. Deep venous thrombosis of right calf. 2. Pulmonary thromboembolus. 3. Obesity (BMI of 42). 4. Bilateral adrenal hyperplasia. 5. Histological changes in thyroid suggestive of Hashimoto's disease. 6. Fatty liver.
16/12/2002	Electrographics				Echocardiogram was normal in july 2001.

Additional Information:

P/h of obesity.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173680 **Seq:** 1
Reported: 15/03/2002
Hospitalisation:
Onset Date: 28/02/2002
Outcome: Death

Gender: F
Weight: 0.00
Age: 54
DOB: 31/05/1947
Causality: Causality possible

Reaction Details:

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)		**Reason:**	
	40.0 Milligram	Daily	
Batch:	**Started:**		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	
Tablet	550.0 Milligram	Daily	Oral
Batch:	**Started:** 08/02/1999		**Stopped:** 27/02/2002

Laboratory Investigations:

Additional Information:

P/h of obesity.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173817 **Seq:** 1
Reported: 22/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 31/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 37
DOB: 12/07/1964
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia			Clozapine ceased. patient hospitalised. given iv fluids and paracetamol date of recovery 20/02/2002.

Medicine Details:

SODIUM VALPROATE (Other drug)			**Reason:**	
Tablet	1.0	Gram	Daily	Oral
Batch:	**Started:**			**Stopped:**
OLANZAPINE (Other drug)			**Reason:**	
Oral application	10.0	Milligram	Daily	Oral
Batch:	**Started:**			**Stopped:**
CLOPINE (Suspected)			**Reason:**	
Tablet	250.0	Milligram	Daily	Oral
Batch:	**Started:**	25/01/2002		**Stopped:** 03/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173959 **Seq:** 1 **Gender:** M
Reported: 21/03/2002 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 28/02/2002 **DOB:** 09/01/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Nausea Vomiting			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 14/01/2002 **Stopped:** 07/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		14/02/2002	302	
	ALT = SGPT		20/02/2002	184	
	ALT = SGPT		21/02/2002	277	
	ALT = SGPT		27/02/2002	378	
	ALT = SGPT		28/02/2002	210	
	ALT = SGPT		01/03/2002	415	
	AST = SGOT		14/02/2002	85	

Additional Information:

Patient also experienced hepatitis c. the hepatitis c may have been presented before the clozaril therapy however, it was only just diagnosed. patient also taking thymine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173959 **Seq:** 1 **Gender:** M
Reported: 21/03/2002 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 28/02/2002 **DOB:** 09/01/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

COGENTIN (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	Schizophrenia
Tablet	225.0 Milligram	Daily		Oral
Batch:	**Started:** 14/01/2002		**Stopped:**	07/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT		20/02/2002	49	
	AST = SGOT		27/02/2002	151	
	AST = SGOT		01/03/2002	130	
	AST = SGOT		28/02/2002	55	
	AST = SGOT		21/02/2002	69	
	GGT = SGGT =		14/02/2002	67	
	GGT = SGGT =		20/02/2002	49	

Additional Information:

Patient also experienced hepatitis c. the hepatitis c may have been presented before the clozaril therapy however, it was only just diagnosed. patient also taking thymine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173959 **Seq:** 1 **Gender:** M
Reported: 21/03/2002 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 28/02/2002 **DOB:** 09/01/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

COGENTIN (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
DIAZEPAM (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	Schizophrenia
Tablet	225.0 Milligram	Daily	Oral
Batch:	**Started:** 14/01/2002		**Stopped:** 07/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT = SGOTP		21/02/2002	59	
	GGT = SGGT = SGOTP		27/02/2002	63	
	GGT = SGGT = SGOTP		01/03/2002	64	
	GGT = SGGT = SGOTP		28/02/2002	52	
	SAP = ALP		14/02/2002	139	
	SAP = ALP		20/02/2002	117	
	SAP = ALP		21/02/2002	97	

Additional Information:

Patient also experienced hepatitis c. the hepatitis c may have been presented before the clozaril therapy however, it was only just diagnosed. patient also taking thymine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173959 **Seq:** 1 **Gender:** M
Reported: 21/03/2002 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 28/02/2002 **DOB:** 09/01/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

COGENTIN (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	Schizophrenia
Tablet	225.0 Milligram	Daily		Oral
Batch:	**Started:** 14/01/2002		**Stopped:**	07/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		27/02/2002	132	
	SAP = ALP		28/02/2002	85	
	SAP = ALP		01/03/2002	124	

Additional Information:

Patient also experienced hepatitis c. the hepatitis c may have been presented before the clozaril therapy however, it was only just diagnosed. patient also taking thymine.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173966 **Seq:** 1
Reported: 19/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 19/12/2001
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 80
DOB: 18/05/1921
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction			Patient admitted to hospital, given b blocker.

Medicine Details:

FERRO-GRADUMET (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

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

COLOXYL WITH SENNA (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: lvf, parkinson, delusional disorder, turp, l) cva, anaemia, ihd, multiple falls, laminectomy, aortitis stenosis. patient died 5/2/02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173966 **Seq:** 1
Reported: 19/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 19/12/2001
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 80
DOB: 18/05/1921
Causality: Causality possible

Reaction Details:

Medicine Details:

LACTULOSE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
MADOPAR (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CLOZAPINE (Suspected)		**Reason:**	
	25.0 Milligram	Daily	
Batch:	**Started:** 01/01/2000		**Stopped:**

Laboratory Investigations:

Additional Information:

Patient history: Ivf, parkinson, delusional disorder, turp, l) cva, anaemia, ihd, multiple falls, laminectomy, aortitis stenosis. patient died 5/2/02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173976 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 05/03/2002
Outcome: Recovered

Gender: M
Weight: 80.00
Age: 37
DOB: 14/10/1964
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Eosinophilia Leukocytosis Myocarditis Troponin increased			Patient was hospitalised in intensive care. clozaril discontinued. treated with prednisolone.

Medicine Details:

LOSEC (Other drug) **Reason:**
0.0
Batch: **Started:** 26/10/1999 **Stopped:**

LITHIUM CARBONATE (Other drug) **Reason:**
0.0
Batch: **Started:** 04/08/1999 **Stopped:**

BENZTROPINE MESYLATE (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

COLOXYL WITH SENNA (Other drug) **Reason:** Constipation
2.0 Dose Unspecified Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				13/04/02 - chest x - ray revealed that the patien's heart was of normal size.
	Neutrophils		12/02/2002	7.98X10?9*	*pretreatment
	Neutrophils		05/03/2002	16.67X10?9	*pretreatment
	Neutrophils		06/03/2002	18.68X10?9	*pretreatment
	Troponin				Troponin elevated - 14.03.02; date unknown - 1.3; 1;
	White blood cells		12/02/2002	12.6X10?9*	*pretreatment

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173976 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 05/03/2002
Outcome: Recovered

Gender: M
Weight: 80.00
Age: 37
DOB: 14/10/1964
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 12/02/2002 **Stopped:** 05/03/2002

CISAPRIDE (Suspected) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 26/10/1999 **Stopped:** 08/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		05/03/2002	23.8X10?9	*pretreatment
	White blood cells		06/03/2002	24X10?9/L	*pretreatment

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173977 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 11/03/2002
Outcome: Recovered

Gender: F
Weight:
Age: 27
DOB: 29/11/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			Patient was hospitalised. clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 175.0 Milligram Daily Oral

Batch: **Started:** 31/05/1994 **Stopped:** 21/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		22/02/2002	1.6X10?9/L	
	Neutrophils		01/03/2002	1.6X10?9/L	
	Neutrophils		07/03/2002	0.6X10?9/L	
	Neutrophils		05/03/2002	0.9X10?9/L	
	White blood cells		22/02/2002	2.8X10?9/L	
	White blood cells		01/03/2002	2.7X10?9/L	
	White blood cells		05/03/2002	1.8X10?9/L	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173977 **Seq:** 1
Reported: 21/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 11/03/2002
Outcome: Recovered

Gender: F
Weight:
Age: 27
DOB: 29/11/1974
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	175.0 Milligram	Daily		Oral
Batch:	**Started:** 31/05/1994		**Stopped:**	21/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		07/03/2002	1.6X10?9/L	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173991 **Seq:** 1 **Gender:** M
Reported: 27/03/2002 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 28/02/2002 **DOB:** 10/11/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lymphopenia Thrombocytopenia			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 10/07/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Lymphocytes	1.0 - 4.0	25/03/2002	0.8	
	Lymphocytes	1.0 - 4.0	12/04/2002	0.9	
	Lymphocytes	1.0 - 4.0	22/04/2002	0.9	
	Platelets	150 - 450	25/03/2002	117	
	Platelets	150 - 450	12/04/2002	125	
	Platelets	150 - 450	22/04/2002	130	

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in feb 2002.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173992 **Seq:** 1
Reported: 27/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 07/02/2002
Outcome: Unknown

Gender: F
Weight:
Age: 47
DOB: 16/11/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Asthenia Confusional state Diabetes mellitus Hyperglycaemia Hyperhidrosis Ketosis Pyrexia			Patient hospitalised. treated with oral hypoglycaemics.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 22/01/2002 **Stopped:** 08/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose		23/11/2001	10.2	
	Serum glucose		02/03/2002	10.9	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173993 **Seq:** 1
Reported: 27/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/01/2002
Outcome: Recovered

Gender: M
Weight:
Age: 16
DOB: 08/01/1986
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia Polydipsia Polyuria		Blood glucose abnormal	Patient hospitalised. treated with metformin.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	300.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/01/2001		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose		01/01/2002	6.4	
	Serum glucose		01/03/2002	11.2	

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in january 2002. the dose start date for clozaril is not accurate but indicates the drug was commenced sometime in 2001. risk factor for diabetes: obesity and a family history of diabetes, alcoholism

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 173998 **Seq:** 1
Reported: 27/03/2002
Hospitalisation: Admitted to hospital
Onset Date: 18/03/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 49
DOB: 31/12/1952
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Clozaril ceased until symptoms of overdose ceased. regular small doses of haloperidol for psychosis. required admission to icu, monitoring of bp, temperature, heart rate and fbc monitored.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 50.0 Dose Unspecified Total Oral
Batch: **Started:** 18/03/2002 **Stopped:** 18/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient overdosed on clozaril (approx 50 tablets). normal dose is 275mg daily patient presented with symptoms of delirium, hypersalivation, confusion, slurred speech.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174070 **Seq:** 1 **Gender:** F
Reported: 27/03/2002 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: **DOB:** 29/02/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 25/11/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174080 **Seq:** 1 **Gender:** M
Reported: 21/02/2002 **Weight:** 0.00
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 12/01/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia Hyperlipidaemia			

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
700.0 Milligram Daily Oral
Batch: **Started:** 14/02/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Serum glucose	3.5 - 6.1	04/05/2005	6.6	Fasting blood glucose

Additional Information:

Family history grandparent - diabetes mellitus.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174081 **Seq:** 1 **Gender:** F
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 28/09/2001 **DOB:** 06/01/1961
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			The reaction was treated with diet and exercise.

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				28/09/01 random glucose level = 10.9; 26/10/01 fasting glucose level = 6.5 06/12/01 glucose tolerance test (fasting) = 6.1; 2 hour = 16.2

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174081 **Seq:** 1
Reported: 21/02/2002
Hospitalisation:
Onset Date: 28/09/2001
Outcome: Not yet recovered

Gender: F
Weight:
Age: 40
DOB: 06/01/1961
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet	450.0 Milligram	Daily	Oral

Batch: **Started:** 13/06/1995 **Stopped:**

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174082 **Seq:** 1 **Gender:** M
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 08/05/1970
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			Daonil, change in diet and exercise.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 14/05/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				Random glucose = 15.0 - 28/08/00

Additional Information:

Family history of diabetes.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174083 **Seq:** 1 **Gender:** F
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 09/05/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			Metformin

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 15/10/1999 **Stopped:** 09/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose		26/07/2001	8.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174084 **Seq:** 1 **Gender:** M
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 14/06/2001 **DOB:** 28/04/1964
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Hyperglycaemia			Diabetic diets and exercise program.

Medicine Details:

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

LITHIUM CARBONATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 25/08/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				14/06/01 -fasting glucose 13.4 consistent with the diagnosis diabetes mellitus

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174085 **Seq:** 1 **Gender:** M
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: **DOB:** 24/09/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 275.0 Milligram Daily Oral
Batch: **Started:** 19/04/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose				30/10/01 - fasting blood sugar level 7.0

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174086 **Seq:** 1 **Gender:** M
Reported: 21/02/2002 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 31/05/2001 **DOB:** 08/08/1962
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased			Clozaril was discontinued but was recommenced on 8/9/01 due to poor response to replacement anti-psychotic therapy.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 08/06/1999 **Stopped:** 28/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		01/06/1999	6.8	
	Neutrophils		31/05/2001	6.0	
	Neutrophils		14/06/2001	4.8	
	Troponin		06/08/2001	0.4	
	Troponin		07/09/2001	0.2	
	Troponin		01/10/2001	0.5	
	Troponin		19/11/2001	1.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174086 **Seq:** 1
Reported: 21/02/2002
Hospitalisation:
Onset Date: 31/05/2001
Outcome: Not yet recovered

Gender: M
Weight:
Age: 38
DOB: 08/08/1962
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 08/06/1999 **Stopped:** 28/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin		14/01/2002	0.4	
	White blood cells		01/06/1999	10.4	
	White blood cells		31/05/2001	8.5	
	White blood cells		14/06/2001	7.4	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174153 **Seq:** 1 **Gender:** M
Reported: 02/04/2002 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 01/02/2002 **DOB:** 05/05/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Eosinophilia Granulocytosis Leukocytosis Tachycardia			

Medicine Details:

LITHIUM CARBONATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 25/01/2002 **Stopped:** 12/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils		24/12/2001	0.32	
	Eosinophils		12/03/2002	3.01	
	Eosinophils		20/03/2002	0.53	
	Neutrophils		24/12/2001	12.2	
	Neutrophils		12/03/2002	11.5	
	White blood cells		24/12/2001	15.4	
	White blood cells		12/03/2002	18.1	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174158 **Seq:** 1 **Gender:** M
Reported: 14/02/2002 **Weight:**
Hospitalisation: **Age:** 45
Onset Date: 28/08/2001 **DOB:** 13/06/1956
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified psychosis

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 25/08/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose		14/10/2001	10.2	Blood sugar level.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. patient history: patient had non insulin-dependent diabetes.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174186 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 11/03/2002
Outcome: Recovered

Gender: M
Weight:
Age: 24
DOB: 10/05/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient hospitalised. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected)		**Reason:**	
Tablet	0.0		Oral
Batch:	**Started:** 01/03/1999		**Stopped:**
EPILIM (Suspected)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CIPRAMIL (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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174187 **Seq:** 1 **Gender:** M
Reported: 02/04/2002 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: **DOB:** 19/12/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 10/08/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils				Nc = 1.1

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174214 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 36
DOB: 15/04/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased		C-reacive protein increased.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 26/02/2002 **Stopped:** 12/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Biochemistry		03/09/2003	120	
17/12/2002	Creatine		03/09/2003	512	
01/04/2002	Eosinophils				Eosinophils increased (0.22 to 0.61)
01/04/2002	Erythrocyte				ESR - 75
01/04/2002	Lymphocytes				Lymphocytes decreased (2.85 to 1.56)

Additional Information:

Schizoaffective d/o. Pulmonary embolism and deep vein thrombosis-stable at initiation. Sodium valproate and warfarin. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174214 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 36
DOB: 15/04/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		The patient complained of feeling generally unwell and 'flu-ey', followed by dyspnoea and/or chest pain. She was diagnosed with myocarditis, at which time she was febrile, tachycardic, hypotensive and tachypneic. She demonstrated via Echo a tendency to high-normal wall thicknesses and low-normal ejection fraction. Evidence of an emerging inflammatory or allergic process was also seen through elevated ESR and elevations in C-reactive protein. Also demonstrated were increases in eosinophil count from baseline ...	Patient had been in hospital since jan 2002. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 26/02/2002 **Stopped:** 12/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/04/2002	Radiololgy				The echocardiography showed lapentric hypertrophy. ECG increased rate, minor nonspecific T wave abnormalities. Echo - increased LV wall thickness and indeterminate diastolic function.
01/04/2002	Serum drug level	400 - 1000mcg/L			Clozapine - 110

Additional Information:

Schizoaffective d/o. Pulmonary embolism and deep vein thrombosis-stable at initiation. Sodium valproate and warfarin. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174214 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 36
DOB: 15/04/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Chest pain Dizziness Dyspnoea Ejection fraction decreased Eosinophil count increased Hypotension Malaise Pyrexia		... and decreases in lymphocyte count from baseline.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 26/02/2002 **Stopped:** 12/03/2002

Laboratory Investigations:

Additional Information:

Schizoaffective d/o. Pulmonary embolism and deep vein thrombosis-stable at initiation. Sodium valproate and warfarin. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174214 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 36
DOB: 15/04/1965
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Red blood cell sedimentation rate i			
Tachycardia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	250.0 Milligram	Daily	Oral
Batch:	**Started:** 26/02/2002	**Stopped:**	12/03/2002

Laboratory Investigations:

Additional Information:

Schizoaffective d/o. Pulmonary embolism and deep vein thrombosis-stable at initiation. Sodium valproate and warfarin. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174215 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 13/03/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 58
DOB: 27/03/1943
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness Electrocardiogram abnormal Myocarditis Orthostatic hypotension Tachycardia			Clozapine ceased, patient hospitalised

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
225.0 Milligram Daily Oral
Batch: **Started:** 21/02/2002 **Stopped:** 13/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Chest X-ray				
17/12/2002	Creatine kinase MB		04/03/2002	342	
17/12/2002	Creatine phosphokinase		13/03/2002	354	
17/12/2002	Creatine phosphokinase		14/03/2002	417	
17/12/2002	Creatine phosphokinase		16/03/2002	386	
17/12/2002	Creatine phosphokinase		17/03/2002	386	
17/12/2002	Creatine kinase MB		15/03/2002	367	

Additional Information:

Not history of cardiac disease, but she is a smoker.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174215 **Seq:** 1
Reported: 02/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 13/03/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 58
DOB: 27/03/1943
Causality: Causality possible

Reaction Details:

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
225.0 Milligram Daily Oral
Batch: **Started:** 21/02/2002 **Stopped:** 13/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Electrocardiograph				
17/12/2002	Troponin		04/03/2002	2.4	
17/12/2002	Troponin		13/03/2002	1.1	
17/12/2002	Troponin		14/03/2002	6.6	
17/12/2002	Troponin		15/03/2002	4.3	
17/12/2002	Troponin		16/03/2002	2.2	
17/12/2002	Troponin		17/03/2002	0.6	

Additional Information:

Not history of cardiac disease, but she is a smoker.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174264 **Seq:** 1
Reported: 08/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 25/03/2002
Outcome: Recovered

Gender: F
Weight:
Age: 47
DOB: 30/11/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Dizziness Fatigue Headache Meningitis Pain Pyrexia			Clozapine stopped. treated with antibiotics. date of recovery 29/03/02. patient hospitalised.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
125.0 Milligram Daily
Batch: **Started:** 06/03/2002 **Stopped:** 25/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174276 **Seq:** 1
Reported: 08/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 26/03/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 19
DOB: 11/02/1983
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Syncope			Clopine ceased. admitted to hospital.

Medicine Details:

CLOPINE (Suspected) **Reason:**

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 11/03/2002 **Stopped:** 27/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174282 **Seq:** 1 **Gender:** M
Reported: 08/04/2002 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 19/03/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Required Specialist Consultation	Mild tachycardia.	

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 900.0 Milligram Daily Oral
Batch: **Started:** 02/03/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Current condition - angina pectoris.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174284 **Seq:** 1
Reported: 08/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 19/03/2002
Outcome: Recovered

Gender: M
Weight:
Age: 48
DOB: 19/12/1953
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Patient hospitalised. clozaril discontinued.

Medicine Details:

EPILIM (Other drug)			**Reason:**		
Oral application	1.5	Gram	Daily		Oral
Batch:	**Started:**			**Stopped:**	
CEFTRIAXONE (Other drug)			**Reason:**		
Injection	1.0	Gram	Daily		Intravenous
Batch:	**Started:**			**Stopped:**	
ERYTHROMYCIN (Other drug)			**Reason:**		
Injection	500.0	Milligram	Daily		Intravenous
Batch:	**Started:**			**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	Schizophrenia	
Tablet	600.0	Milligram	Daily		Oral
Batch:	**Started:**	11/04/1994		**Stopped:**	28/02/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		31/03/1994	6.4	
	Neutrophils		20/02/2002	3.18	
	Neutrophils		19/03/2002	0.94	
	White blood cells		31/03/1994	9.5	
	White blood cells		20/02/2002	5.30	
	White blood cells		19/03/2002	1.60	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174395 **Seq:** 1
Reported: 10/04/2002
Hospitalisation:
Onset Date: 01/03/2002
Outcome: Not yet recovered

Gender: M
Weight: 95.00
Age: 25
DOB: 12/10/1976
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia Neutropenia			Clopine therapy was ceased.

Medicine Details:

ZUCLOPENTHIXOL DECANOATE (Other drug) **Reason:** Schizophrenia
Injection 200.0 Milligram Fortnightly Intramuscular
Batch: **Started:** 20/11/2001 **Stopped:** 31/01/2002

AROPAX (Other drug) **Reason:**
Tablet 60.0 Milligram Daily Oral
Batch: **Started:** 19/11/2001 **Stopped:** CONTIN

SODIUM VALPROATE (Other drug) **Reason:**
Tablet 1.5 Gram Daily Oral
Batch: **Started:** 20/11/2001 **Stopped:** CONTIN

CLOPINE (Suspected) **Reason:** Schizophrenia
Tablet 325.0 Milligram Daily Oral
Batch: **Started:** 01/02/2002 **Stopped:** 01/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils	(0.1-0.5)	27/02/2002	6.10	
	Neutrophils		01/03/2002	1.57	
	Neutrophils		03/03/2002	0.85	
	White blood cells		01/03/2002	8.7	
	White blood cells		03/03/2002	3.40	

Additional Information:

174180 is a duplicate of 174395.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174398 **Seq:** 1 **Gender:** F
Reported: 02/04/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 16/03/2002 **DOB:** 17/09/1961
Outcome: Unrelated death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 19/11/1997 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 16/3/02.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174401 **Seq:** 1 **Gender:** M
Reported: 04/04/2002 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: 18/03/2002 **DOB:** 08/12/1976
Outcome: Unrelated death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 07/01/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174402 **Seq:** 1 **Gender:** M
Reported: 04/04/2002 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 15/03/2002 **DOB:** 25/05/1962
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrioventricular block Bundle branch block			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 27/09/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg showed changes in pr length and bundle branch conduction changes.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174520 **Seq:** 1 **Gender:** M
Reported: 15/04/2002 **Weight:** 85.00
Hospitalisation: **Age:** 31Y
Onset Date: 29/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Tachycardia			Clozapine ceased. date of recovery 13/09/01.

Medicine Details:

MYLANTA (Other drug)			**Reason:** Otr disorders stomach function	
Oral application	20.0 Millilitre		As necessary	Oral
Batch:	**Started:** 09/08/2001		**Stopped:**	CONTIN
LORAZEPAM (Other drug)			**Reason:** Otr spec symp psychopathol nec	
Oral application	1.0 Milligram		As necessary	Oral
Batch:	**Started:** 25/06/2001		**Stopped:**	CONTIN
OMEPRAZOLE (Other drug)			**Reason:** Other diseases of esophagus	
Oral application	40.0 Milligram		Daily	Oral
Batch:	**Started:** 17/08/2001		**Stopped:**	CONTIN
CLOZAPINE (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	550.0 Milligram		Daily	Oral
Batch:	**Started:** 06/08/2001		**Stopped:**	09/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174572 **Seq:** 1 **Gender:** M
Reported: 15/04/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	0.0	Daily	Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174581 **Seq:** 1 **Gender:** F
Reported: 13/03/2002 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: 19/09/2001 **DOB:** 11/08/1946
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash erythematous Neutropenia Oedema		Redness on the legs.	 Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 01/08/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174736 **Seq:** 1 **Gender:** M
Reported: 22/04/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia Weight increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction onset date - 2002.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174737 **Seq:** 1
Reported: 22/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/03/2002
Outcome: Recovered

Gender: M
Weight:
Age: 48
DOB: 26/04/1953
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Neutropenia Sepsis		Body temperature increased.	Patient hospitalised.

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 15/02/2002 **Stopped:** 07/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		15/02/2002	2.5	
	Neutrophils		26/02/2002	3.7	
	Neutrophils		04/03/2002	6.70	
	Neutrophils		03/04/2002	2.20	
	Neutrophils		28/03/2002	2.60	
	Neutrophils		06/03/2002	1.80	
	White blood cells		15/02/2002	5.3	

Additional Information:

The dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174737 **Seq:** 1
Reported: 22/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/03/2002
Outcome: Recovered

Gender: M
Weight:
Age: 48
DOB: 26/04/1953
Causality: Causality possible

Reaction Details:

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 15/02/2002 **Stopped:** 07/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		26/02/2002	6.8	
	White blood cells		04/03/2002	8.30	
	White blood cells		06/03/2002	7.80	
	White blood cells		28/03/2002	5.00	
	White blood cells		03/04/2002	4.70	

Additional Information:

The dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174821 **Seq:** 1
Reported: 24/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 05/04/2002
Outcome: Unknown

Gender: F
Weight:
Age: 70
DOB: 19/03/1932
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Cerebrovascular disorder Dystonia Hypoxia		Myoclonic jerks.	Admitted to hospital.

Medicine Details:

THYROXINE SODIUM (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
VENTOLIN (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
FLIXOTIDE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
SODIUM VALPROATE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest x-ray showed atelectasis in right middle lobe and no other acute changes
	White blood cells		11/03/2002	16.6	
	White blood cells		05/05/2002	23.2	

Additional Information:

Relevant history - chronic obstructive airway disease.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174821 **Seq:** 1
Reported: 24/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 05/04/2002
Outcome: Unknown

Gender: F
Weight:
Age: 70
DOB: 19/03/1932
Causality: Causality possible

Reaction Details:

Medicine Details:

LITHIUM CARBONATE (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**			**Stopped:**
ASPIRIN (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**			**Stopped:**
PREDNISOLONE (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**			**Stopped:**
CLOZARIL (Suspected)			**Reason:**	
Tablet	100.0	Milligram	Daily	Oral
Batch:	**Started:** 11/03/2002			**Stopped:**

Laboratory Investigations:

Additional Information:

Relevant history - chronic obstructive airway disease.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174823 **Seq:** 1
Reported: 24/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/04/2001
Outcome: Unknown

Gender: M
Weight:
Age: 30
DOB: 24/06/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Overdose of clozaril and other drugs.	Admitted to hospital. clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 0.0 Oral

Batch: **Started:** 28/02/2001 **Stopped:** 01/05/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174883 **Seq:** 1 **Gender:** F
Reported: 22/04/2002 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 05/01/1967
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation			Clozaril was discontinued and non-drug treatment with enema was started.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 26/02/2002 **Stopped:** 19/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174884 **Seq:** 1 **Gender:** F
Reported: 22/04/2002 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 05/01/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation			Clozaril ceased. treated with denokot, coloxyl, microlax and travad enemas.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 26/02/2002 **Stopped:** 12/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174910 **Seq:** 1
Reported: 29/04/2002
Hospitalisation: Treated in outpatient department only.
Onset Date: 07/04/2002
Outcome: Unknown

Gender: M
Weight:
Age: 25
DOB: 21/09/1976
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Troponin increased			Treated in the emergency department.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 75.0 Milligram Daily Oral

Batch: **Started:** 04/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				08/04/02 - ecg showed "minor abnormalities" 09/04/02 - ecg had returned to normal.
	Troponin		08/04/2002	0.6	
	Troponin		09/04/2002	0.4	
	Troponin		11/04/2002	<0.3	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174911 **Seq:** 1 **Gender:** M
Reported: 29/04/2002 **Weight:** 120.00
Hospitalisation: **Age:** 35
Onset Date: 01/02/2002 **DOB:** 08/03/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Hyperglycaemia			

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 21/07/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum glucose		12/02/2002	11.4	
	Serum glucose		12/02/2002	21.2	
	Serum glucose		12/02/2002	16.4	

Additional Information:

History of ethanol use. family history (father) of diabetes.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174912 **Seq:** 1
Reported: 29/04/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight:
Age: 52
DOB: 04/01/1950
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension			Patient hospitalised. treated with atenolol.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 01/10/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174945 **Seq:** 1 **Gender:** F
Reported: 29/04/2002 **Weight:**
Hospitalisation: **Age:** 61
Onset Date: 28/02/2002 **DOB:** 31/03/1940
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest Respiratory failure			

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

End stage chronic obstructive airways disease. emphysema for more than 10 year s. smoker - 30 cigarets per day. alcoholic. epilepsy. an autopsy was performed and the cause of death found to be cardiac arrest secondary to respiratory failure.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174945 **Seq:** 1
Reported: 29/04/2002
Hospitalisation:
Onset Date: 28/02/2002
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 61
DOB: 31/03/1940
Causality: Causality possible

Reaction Details:

Medicine Details:

FRUSEMIDE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
RANITIDINE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
BENZTROPINE MESYLATE (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
AUGMENTIN (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**

Laboratory Investigations:

Additional Information:

End stage chronic obstructive airways disease. emphysema for more than 10 year s. smoker - 30 cigarets per day. alcoholic. epilepsy. an autopsy was performed and the cause of death found to be cardiac arrest secondary to respiratory failure.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174945 **Seq:** 1
Reported: 29/04/2002
Hospitalisation:
Onset Date: 28/02/2002
Outcome: Death, maybe drug

Gender: F
Weight:
Age: 61
DOB: 31/03/1940
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	Other&unspecified epilepsy
Tablet	450.0 Milligram	Daily		Oral
Batch:	**Started:** 01/01/2000		**Stopped:**	

Laboratory Investigations:

Additional Information:

End stage chronic obstructive airways disease. emphysema for more than 10 year s. smoker - 30 cigarets per day. alcoholic. epilepsy. an autopsy was performed and the cause of death found to be cardiac arrest secondary to respiratory failure.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 174946 **Seq:** 1 **Gender:** F
Reported: 29/04/2002 **Weight:** 0.00
Hospitalisation: **Age:** 65
Onset Date: **DOB:** 26/09/1936
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure Pneumonia Respiratory failure			Treated with Augmentin Duo Forte on 26/03/2002. Patient died on 27/03/02.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 30/10/1998 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of onset March 2002. Long history of smoking and chronic schizophrenia. Right lower lobe pneumonia. Chronic obstryctive airways disease. Patient also taking temazepam, paxam. Underlying conditions provide a possible explanation for the reported adverse event.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175043 **Seq:** 1 **Gender:** M
Reported: 01/05/2002 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 06/03/2002 **DOB:** 08/09/1951
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 550.0 Milligram Daily Oral

Batch: **Started:** 24/01/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		06/03/2002	0.4	
	White blood cells		06/03/2002	2.30	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175129 **Seq:** 1 **Gender:** M
Reported: 06/05/2002 **Weight:** 0.00
Hospitalisation: **Age:** 25
Onset Date: 22/03/2002 **DOB:** 18/01/1977
Outcome: Death 22/03/2002 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Sudden death	Life threatening		

Medicine Details:

DROPERIDOL (Suspected) **Reason:**
Injection As necessary Intramuscular
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 03/08/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/05/2002	Autopsy report				

Additional Information:

Patient died approximately 2 and half years after commencing Clozaril. He had been receivine droperidol for some time and had received an IM injection half an hour prior to his death.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175132 **Seq:** 1 **Gender:** M
Reported: 02/04/2002 **Weight:**
Hospitalisation: **Age:** 22
Onset Date: **DOB:** 14/01/1980
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			Clozaril therapy was reduced as a measure to treat the symptom.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 01/08/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history - heroin and alcohol abuse. the dose start date for the drug clozaril is not necessarily accurate but indicates the drug was started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175141 **Seq:** 1 **Gender:** M
Reported: 04/04/2002 **Weight:**
Hospitalisation: **Age:** 18
Onset Date: 28/08/2001 **DOB:** 30/09/1982
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			Clozaril dose was reduced to 200mg as a measure to treat the reaction. patient required a visit to urologist.

Medicine Details:

ATENOLOL (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 16/01/2002

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 250.0 Milligram Daily Oral
Batch: **Started:** 01/08/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175204 **Seq:** 1 **Gender:** F
Reported: 06/05/2002 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 28/04/1958
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Retinal disorder		Retinal toxicity, pigment epithelial atrophy.	Melleril was discontinued.

Medicine Details:

MELLERIL (Suspected)		**Reason:** Unspecified schizophrenia		
Tablet	0.0		Oral	
Batch:	**Started:** 01/01/1994		**Stopped:**	
CLOZAPINE (Suspected)		**Reason:** Unspecified schizophrenia		
Tablet	450.0 Milligram	Daily	Oral	
Batch:	**Started:** 27/07/1994		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Erg (an electroretinogram) showed that the patient's retina was grossly abnormal and significantly extinguished.
	Other data				The reporter stated that the patient suffered from extensive retinal pigment epithelial apathy.

Additional Information:

The dose start date for melleril is not accurate but indicates the drug was started sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175205 **Seq:** 1 **Gender:** F
Reported: 06/05/2002 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 15/04/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Body twisting movements.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 24/03/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175207 **Seq:** 1 **Gender:** M
Reported: 06/05/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 01/01/2001 **DOB:** 28/09/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperadrenocorticism		Isolated rise in noradrenaline.	

Medicine Details:

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

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

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

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 900.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				(date unknown): 24 hour noradrenaline 1363 umol/day (normal value<785).

Additional Information:

Patients 24 hour noradreniline was 1363 umol/day. the date of onset is not accurate but indicates onset sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175214 **Seq:** 1 **Gender:** F
Reported: 06/05/2002 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: 10/04/2002 **DOB:** 10/11/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			

Medicine Details:

DOTHIEPIN HYDROCHLORIDE (Other drug) **Reason:**
Oral application 225.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

RISPERIDONE (Other drug) **Reason:**
Oral application 6.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

SODIUM VALPROATE (Other drug) **Reason:**
Oral application 1.5 Gram Daily Oral
Batch: **Started:** L TERM **Stopped:**

CLOZAPINE (Suspected) **Reason:**
Tablet 800.0 Milligram Daily Oral
Batch: **Started:** 06/03/1997 **Stopped:** 12/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		10/04/2002	1.0	
	White blood cells		10/04/2002	2.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175225 **Seq:** 1 **Gender:** F
Reported: 07/05/2002 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 01/02/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Treated with filgrastim 300mcg daily for 8 days. clozapine, flupenthixol and chlorpromazine ceased.

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected) **Reason:**
Injection 40.0 Milligram Fortnightly Intravenous
Batch: **Started:** **Stopped:** 21/01/2002

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** 14/07/1997 **Stopped:** 21/01/2002

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:** Anxiety neurosis
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 21/01/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		07/03/2002	0.6	
	Neutrophils		16/03/2002	11.7	
	White blood cells		07/03/2002	1.6	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175314 **Seq:** 1 **Gender:** M
Reported: 10/05/2002 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: 18/04/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Supraventricular tachycardia Syncope			

Medicine Details:

SODIUM VALPROATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Electrocardiography showed supraventricular tachycardia.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175315 **Seq:** 1 **Gender:** M
Reported: 10/05/2002 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 19/04/2002 **DOB:** 10/11/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mitral valve incompetence			

Medicine Details:

SODIUM VALPROATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

DIAZEPAM (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 01/01/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175318 **Seq:** 1 **Gender:** F
Reported: 13/05/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 16Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Dyspnoea Pericarditis Troponin increased		Pleuritic chest pain	Paracetamol 1 gm.

Medicine Details:

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

DIAZEPAM (Other drug) **Reason:** Specific disorders of sleep
Oral application 2.0 Milligram As necessary Oral
Batch: **Started:** **Stopped:**

BENZTROPINE MESYLATE (Other drug) **Reason:**
Oral application 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph Troponin				Ecg revealed p-mitrale in lead i, t-wave flattening in lead iii, st-segment elevation concave upward across all leads, and biphasic p-wave in vi. Serum troponin i of 1.89 micrograms/l.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175323 **Seq:** 1 **Gender:** F
Reported: 10/05/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 19/04/2002 **DOB:** 18/10/1952
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death			Patient died on 19/04/02, approx 3 years and 9 months after commencing clozapine.

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Autopsy performed. the reporter causality was given as unlikely.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175323 **Seq:** 1 **Gender:** F
Reported: 10/05/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 19/04/2002 **DOB:** 18/10/1952
Outcome: Death **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	
Tablet	425.0 Milligram		Daily	Oral
Batch:	**Started:** 02/07/1998		**Stopped:**	19/04/2002

Laboratory Investigations:

Additional Information:

Autopsy performed. the reporter causality was given as unlikely.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175334 **Seq:** 1
Reported: 08/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 22/03/2002
Outcome: Recovered

Gender: F
Weight: 52.00
Age: 47
DOB: 30/11/1954
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Lymphopenia		Lymphocyte count decreased	
Neutropenia		Neutrophil count decreased	
Chills			Patient was admitted to hospital. date of recovery 29/03/02
Fatigue			
Headache			
Hypersensitivity			
Malaise			
Pain			
Polydipsia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 08/03/2002 **Stopped:** 25/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Lymphocytes	0.9 - 4.0	25/03/2002	0.3	
	Neutrophils		06/03/2002	3.3	
	Neutrophils		18/03/2002	4.70	
	Neutrophils		25/03/2002	2.80	
	Neutrophils		29/03/2002	2.50	
	Neutrophils		28/03/2002	1.60	
	Neutrophils		27/03/2002	0.80	

Additional Information:

Other reaction terms: dizziness, rash.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175334 **Seq:** 1
Reported: 08/04/2002
Hospitalisation: Admitted to hospital
Onset Date: 22/03/2002
Outcome: Recovered

Gender: F
Weight: 52.00
Age: 47
DOB: 30/11/1954
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 08/03/2002 **Stopped:** 25/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		06/03/2002	4.5	
	White blood cells		18/03/2002	5.7	
	White blood cells		25/03/2002	3.20	
	White blood cells		27/03/2002	1.30	
	White blood cells		28/03/2002	2.20	
	White blood cells		29/03/2002	3.50	

Additional Information:

Other reaction terms: dizziness, rash.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175372 **Seq:** 1
Reported: 10/05/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight:
Age: 51
DOB: 11/03/1951
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection Salivary hypersecretion Somnolence		Intercurrent infections.	Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 29/09/1998 **Stopped:** 22/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175373 **Seq:** 1
Reported: 10/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 26/04/2002
Outcome: Unknown

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

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Severe	Severe gastric pain.	Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 0.0 Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175424 **Seq:** 1 **Gender:** M
Reported: 10/05/2002 **Weight:** 100.00
Hospitalisation: **Age:** 37
Onset Date: 04/04/2002 **DOB:** 09/02/1965
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness Pyrexia			Required a visit to doctor. date of recovery 10.4.02.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
150.0 Milligram Daily
Batch: **Started:** 01/02/2002 **Stopped:** 04/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175455 **Seq:** 1
Reported: 10/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/04/2002
Outcome: Not yet recovered

Gender: F
Weight: 47.00
Age: 22
DOB: 17/09/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Tachycardia			Patient was hospitalised. treated with ramipril 1.25mg and metoprolol 125mg bd.

Medicine Details:

DIAZEPAM (Other drug) **Reason:** Specific disorders of sleep
5.0 Milligram Daily
Batch: **Started:** 10/04/2002 **Stopped:**

ZUCLOPENTHIXOL ACETATE (Other drug) **Reason:**
200.0 Milligram Daily
Batch: **Started:** 27/03/2002 **Stopped:**

CLOZAPINE (Suspected) **Reason:**
200.0 Milligram Daily
Batch: **Started:** 15/04/2002 **Stopped:** 29/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175541 **Seq:** 1
Reported: 16/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 09/04/2002
Outcome: Unknown

Gender: F
Weight:
Age: 47
DOB: 28/09/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			Patient was hospitalised.

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		16/04/2002	1.8	
	Neutrophils		19/04/2002	1.7	
	Neutrophils		30/04/2002	2.0	
	Neutrophils		23/04/2002	1.9	
	White blood cells		16/04/2002	3.1	
	White blood cells		19/04/2002	2.9	
	White blood cells		23/04/2002	3.0	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175541 **Seq:** 1
Reported: 16/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 09/04/2002
Outcome: Unknown

Gender: F
Weight:
Age: 47
DOB: 28/09/1954
Causality: Causality possible

Reaction Details:

Medicine Details:

HYDRENE 25/50 (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

THYROXINE SODIUM (Other drug) **Reason:**
Tablet 50.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

TRANYLCYPROMINE SULPHATE (Other drug) **Reason:**
Tablet 40.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 04/01/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		30/04/2002	3.1	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175560 **Seq:** 1
Reported: 17/05/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 43
DOB: 22/07/1958
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased Psychotic disorder Therapeutic response decreased			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 22/07/1993 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2002	Serum drug level		04/08/2003	1215 UG/L	Clozapine
16/12/2002	Serum drug level		04/08/2003	1273 UG/L	Clozapine
16/12/2002	Serum drug level		04/08/2003	379 UG/L	Norclozapine
16/12/2002	Serum drug level		04/08/2003	727 UG/L	Norclozapine
16/12/2002	White blood cells		04/08/2003	11.9	
16/12/2002	White blood cells		04/08/2003	11.10	
16/12/2002	White blood cells		04/08/2003	11.00	

Additional Information:

Patient has had 6 admissions to hospital since jul 2001, due to spychotic relapse.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175610 **Seq:** 1 **Gender:** F
Reported: 21/05/2002 **Weight:** 70.00
Hospitalisation: **Age:** 38
Onset Date: **DOB:** 12/03/1964
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bundle branch block Electrocardiogram QT prolonged Electrocardiogram abnormal Leukocytosis			

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 25/11/1993 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175611 **Seq:** 1
Reported: 21/05/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 22
DOB: 17/09/1979
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		The patient complained of feeling generally unwell and 'flu-ey', followed by dyspnoea and/or chest pain. She was diagnosed with myocarditis, at which time she was febrile, tachycardic, hypotensive and tachypneic. She demonstrated via Echo a tendency to high-normal wall thicknesses and low-normal ejection fraction. Evidence of an emerging inflammatory or allergic process was also seen through elevated ESR and elevations in C-reactive protein. Also demonstrated were increases in eosinophil count from baseline ...	Clozaril ceased. Improved over next severeal days with supportive care and treatment with ramipril and metoprolol.

Medicine Details:

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

FLUPENTHIXOL DECANOATE (Other drug) **Reason:**
0.0
Batch: **Started:** 01/04/2002 **Stopped:**

BENZTROPINE MESYLATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Biochemistry	<5	02/09/2003	130	
21/05/2002	C-Reactive Protein				CRP - 140
17/12/2002	Creatine [illegible]	<160	02/09/2003	285	
21/05/2002	Electrocardiograph				ECG rate increased, generalised nonspecific T wave abnormalities. Echo - low-normal LV function that improved over time.
17/12/2002	Eosinophils	2%	02/09/2003	0.14	

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. Clozapine dose 12.5mg/day yp to 200mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175611 **Seq:** 1
Reported: 21/05/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 22
DOB: 17/09/1979
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr C-reactive protein increased Chest pain Dyspnoea Ejection fraction decreased Electrocardiogram abnormal Eosinophil count increased Hypotension Malaise		... and decreases in lymphocyte count from baseline.	

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 11/04/2002 **Stopped:** 29/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Erythrocyte sedimentation rate	<20	02/09/2003	40	
21/05/2002	Lymphocytes				Lymphocytes decreased (1.79 to 0.89).
21/05/2002	Serum drug level				Clozapine - 470

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. Clozapine dose 12.5mg/day yp to 200mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175611 **Seq:** 1
Reported: 21/05/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 22
DOB: 17/09/1979
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations Pyrexia Red blood cell sedimentation rate i Tachycardia Troponin increased			

Medicine Details:

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

FLUPENTHIXOL DECANOATE (Other drug) **Reason:**
0.0
Batch: **Started:** 01/04/2002 **Stopped:**

BENZTROPINE MESYLATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

Laboratory Investigations:

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. Clozapine dose 12.5mg/day yp to 200mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175611 **Seq:** 1
Reported: 21/05/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 22
DOB: 17/09/1979
Causality: Causality probable

Reaction Details:

Medicine Details:

TEMAZEPAM (Other drug)		**Reason:**	
	0.0		
Batch:	**Started:**		**Stopped:**
CLOZARIL (Suspected)		**Reason:**	
Tablet	25.0 Milligram	Daily	Oral
Batch:	**Started:** 11/04/2002		**Stopped:** 29/04/2002

Laboratory Investigations:

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. Clozapine dose 12.5mg/day yp to 200mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175640 **Seq:** 1 **Gender:** M
Reported: 22/05/2002 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: **DOB:** 09/02/1965
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased			

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 20/03/2002 **Stopped:** 17/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175642 **Seq:** 1 **Gender:** M
Reported: 23/05/2002 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: 28/06/2001 **DOB:** 01/04/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations Tachycardia			Patient was treated with propranolol(20mg, tds) and verapamil (180mg, bid).

Medicine Details:

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

CLOPINE (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Ecg showed sinus tachycardia.

Additional Information:

Therapy dates: 11-sep-2001 to 2-jan-2002/2-jan-2002 to 22-apr-2002/22-apr-02.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175644 **Seq:** 1
Reported: 23/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 08/04/2002
Outcome: Recovered

Gender: F
Weight: 79.00
Age: 41
DOB: 20/09/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis C-reactive protein increased Cardiac failure		Patient experienced a Clozapine-related myocarditis, complained of feeling generally unwell and fluey, dyspnoea and/or chest pain, febrile (38.4), tachycardic. There was evidence of heart failure and small pleural effusions. Her echo demonstrated a reduced ejection fraction and evidence of elevated EST and elevations in C-reactive protein. There was also an increase in the eoxinophil count.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
300.0 Milligram Daily Oral
Batch: **Started:** 20/03/2002 **Stopped:** 08/04/2002

LUVOX (Suspected) **Reason:** Schizophrenia
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/05/2002	C-Reactive Protein				CRP: 246 (11/04/2002)
23/05/2002	Chest X-ray				07/04/2002: Heart size normal limits. Small left basal pleural effusion and some linear markings at both lung bases consistent with small areas of scarring or subsequent collapse.

Additional Information:

Clozapine started 12.5mg up to 300mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175644 **Seq:** 1
Reported: 23/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 08/04/2002
Outcome: Recovered

Gender: F
Weight: 79.00
Age: 41
DOB: 20/09/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cough			
Dyspnoea			
Ejection fraction decreased			
Electrocardiogram abnormal			
Eosinophil count increased			
Fatigue			
Hepatic function abnormal			
Hypotension			
Leukocytosis			
Pleural effusion			
Productive cough			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
300.0 Milligram Daily Oral
Batch: **Started:** 20/03/2002 **Stopped:** 08/04/2002

LUVOX (Suspected) **Reason:** Schizophrenia
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/05/2002	Echocardiogram				09/04/2002: LV wall thickness mildly increased, global reduction in systolic functioning (EF: 48%). Vlaves were normal.
23/05/2002	Electrocardiograph				08/04/2002: ECG: ST segment straigtening septal leads and non-specific T wave globally.
17/12/2002	Erythrocyte		02/09/2003	110	
17/12/2002	Neutrophils		02/09/2003	11.07	

Additional Information:

Clozapine started 12.5mg up to 300mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175644 **Seq:** 1
Reported: 23/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 08/04/2002
Outcome: Recovered

Gender: F
Weight: 79.00
Age: 41
DOB: 20/09/1960
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Red blood cell sedimentation rate i Tachycardia Troponin increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
300.0 Milligram Daily Oral
Batch: **Started:** 20/03/2002 **Stopped:** 08/04/2002

LUVOX (Suspected) **Reason:** Schizophrenia
300.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	White blood cells		02/09/2003	18.8	

Additional Information:

Clozapine started 12.5mg up to 300mg/day. Eventually published in Australian and New Zealand Journal of Psychlatry. Reinders J, Pasonage W, Lange D, Potter JM, Plever S. Clozapine-related myocarditis and cardiomyopathy in an Australian metropplitan psychiatric service Volume:38 Year:2004 pages:915-922.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175705 **Seq:** 1 **Gender:** F
Reported: 27/05/2002 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 05/09/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Viral infection Influenza like illness Pharyngitis	Severe	Severe viral infection.	

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 30/01/2001 **Stopped:** 28/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		02/05/2002	1.10	
	Neutrophils		04/05/2002	1.50	

Additional Information:

The dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175710 **Seq:** 1 **Gender:** M
Reported: 29/05/2002 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: **DOB:** 19/10/1974
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Accidental overdose Coma Myocardial ischaemia		Mental impairment	Date of death may 2002.

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 650.0 Milligram Daily Oral
Batch: **Started:** 20/01/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Autopsy was performed and showed that the patient died from ischaemic heart disease, evidence of coronary artery disease with an obstructed coronary artery. the patients clozaril therapy was interrupted for two weeks and he was mentall y unwell. he then received a clozaril dose of 650mg. he fell into a coma and died. the doctor indicated that the post mortem showed evidence of coronary artery disease. the cause of death was unknown, however it was not myocarditis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175724 **Seq:** 1 **Gender:** M
Reported: 29/05/2002 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 28/12/2001 **DOB:** 03/12/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased Hepatic function abnormal Suicide attempt			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 01/07/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	7 - 56 U/L	03/10/2000	116	Alanie amino transferase 120
	GGT = SGGT = [illegible]		15/05/2002	201	Gamma gt 140.
	SAP = ALP	30 - 120	03/10/2000	153	Alkaline phosphatase 130.
	SAP = ALP	30 - 120	20/12/2001	132	Alkaline phosphatase 130.
	Serum drug level	350 - 450	22/01/2002	1402	Clozapine concentration

Additional Information:

The dose start date for clozaril is nto necessarily accurate but indicates the drug was started sometime in the month. patient history: alcoholism - the patient was known to be a moderately heavy drinker of alcohol.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175740 **Seq:** 1 **Gender:** M
Reported: 29/05/2002 **Weight:**
Hospitalisation: **Age:** 0
Onset Date: 10/05/2002 **DOB:** 10/05/2002
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Pyrexia			Clozaril dose was reduced to 150mg daily.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 22/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of eps on other antipsychotics.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175759 **Seq:** 1 **Gender:** F
Reported: 29/05/2002 **Weight:**
Hospitalisation: **Age:** 63
Onset Date: 07/05/2002 **DOB:** 07/08/1938
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		High plasma levels of clozapine.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	300.0 Milligram	Daily	Oral	
Batch:	**Started:** 06/08/2001		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Clozaril level was 1580ug/l on the 07/05/2002.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175863 **Seq:** 1 **Gender:** F
Reported: 03/06/2002 **Weight:**
Hospitalisation: **Age:** 44
Onset Date: **DOB:** 10/03/1958
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state Convulsion Urinary incontinence Weight increased			

Medicine Details:

LITHIUM CARBONATE (Other drug)			**Reason:**	
Oral application	750.0	Milligram	Daily	Oral
Batch:	**Started:**		**Stopped:**	
CLOPINE (Suspected)			**Reason:**	
Tablet	300.0	Milligram	Daily	Oral
Batch:	**Started:**	30/08/2001	**Stopped:**	13/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

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

Reaction Details:

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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175866 **Seq:** 1 **Gender:** F
Reported: 03/06/2002 **Weight:**
Hospitalisation: **Age:** 15
Onset Date: 04/04/2002 **DOB:** 13/04/1986
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

CLOZARIL (Interaction)		**Reason:** Schizophrenia		
Tablet	400.0 Milligram	Daily	Oral	
Batch:	**Started:** 01/12/2000		**Stopped:**	CONTIN
SODIUM VALPROATE (Interaction)		**Reason:**		
Tablet	0.0	Daily	Oral	
Batch:	**Started:**		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				4/4/02 clozapine plasma level (1.20 mmol/l)
	Pharmacokinetics				Feb 2002: clozapine level 1.19mmol/l, (date unknown):clozapine level 2.12mmol/ l, 4/4/02 clozapine level 1.20mmol/l. (date unknown)norclozapine level elevated.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175867 **Seq:** 1 **Gender:** M
Reported: 03/06/2002 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 11/04/1947
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 04/03/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 175958 **Seq:** 1 **Gender:** F
Reported: 05/06/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 18/05/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged Electrocardiogram abnormal			Patient hospitalised.

Medicine Details:

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

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Long circuit heart conduction and an increased qt interval.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176003 **Seq:** 1
Reported: 05/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/05/2002
Outcome: Recovered

Gender: M
Weight:
Age: 35
DOB: 22/03/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Enteritis			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 800.0 Milligram Daily Oral

Batch: **Started:** 05/10/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176028 **Seq:** 1 **Gender:** F
Reported: 07/06/2002 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 16Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased		Cardiac troponin i increased.	
Electrocardiogram abnormal		Electrocardiogram p wave abnormal.	
Tachycardia		Pulse rate of 124 beats/min.	
Chest pain			
Dyspnoea			
Palpitations			
Pericarditis			Treated with paracetamol 1gm orally. patient was hospitalised.

Medicine Details:

BENZTROPINE MESYLATE (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

DIAZEPAM (Other drug) **Reason:**
2.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
25.0 Milligram Daily
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				An ecg showed p-mitrale in lead i, t-wave flattening in lead iii, st-segment elevation concave up-war acorss all leads, and a hiphasic p-wave in v1.
	Troponin	<0.4			Serum troponin i of 1.89, decreasing the following day to 0.29. two weeks later, her troponin i level was <0.04.

Additional Information:

24d. report source literature journal: australian and new zealand journal of psychiatry author: kay se, doery j, sholl d title: clozapine associated pericarditis and elevated troponin i volune: 36 year: 2002 pages: 143-144. patient had not history of cardiovascular disease, and was otherwise well. clozapine 25mg daily was commenced 3 weeks prior, and increased to 100mg daily over 2 weeks.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176031 **Seq:** 1 **Gender:** F
Reported: 07/06/2002 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 21/05/2002 **DOB:** 18/01/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebral haemorrhage Convulsion Drug level increased			Clozaril reduced to 350mg daily.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 18/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data Serum drug level				Computer tomography scan of the head showed a small subdural bleed in the left temporal area. no changes were seen in the repeat scan. Clozaril level >1000. (date unknown).

Additional Information:

Patient has no history of seizurs.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176077 **Seq:** 1 **Gender:** M
Reported: 22/04/2002 **Weight:**
Hospitalisation: **Age:** 53
Onset Date: 15/03/2002 **DOB:** 15/05/1948
Outcome: Unknown **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Bronchitis Influenza like illness Neutropenia			Clopine ceased. patient was hospitalised.

Medicine Details:

CLOPINE (Suspected)			**Reason:**	
Tablet	125.0 Milligram		Daily	Oral
Batch:	**Started:** 02/11/2001			**Stopped:** 28/02/2002
SODIUM VALPROATE (Suspected)			**Reason:**	
Oral application	2.0 Gram		Daily	Oral
Batch:	**Started:**			**Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		15/03/2002	1.4	
	Neutrophils		19/03/2002	4.3	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176160 **Seq:** 1 **Gender:** M
Reported: 11/06/2002 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 05/02/2002 **DOB:** 26/06/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia			Date of recovery 7.2.02. chlorpromazine ceased.

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
5.0 Milligram As necessary
Batch: **Started:** 01/02/2002 **Stopped:** CONTIN

CHLORPROMAZINE HYDROCHLORIDE (Suspected) **Reason:**
100.0 Milligram As necessary
Batch: **Started:** 01/02/2002 **Stopped:** 05/02/2002

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
12.5 Milligram Daily
Batch: **Started:** 30/01/2002 **Stopped:** 04/03/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		05/02/2002	1.82	
	White blood cells		05/02/2002	4.7	

Additional Information:

Increasing clozapine dose from 12.5mg on 30.1.02 to 350mg on 7.2.02. non-compliant with clozapine when discharged from hospital.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176327 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: **DOB:** 11/04/1947
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Blood creatine phosphokinase incr Blood pressure fluctuation Confusional state Hypertonia Leukocytosis Neuroleptic malignant syndrome Pyrexia Tremor		Myocarditis or acute coronary syndrome.	Clozapine changed to olanzepine. treated with bromocriptine.

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
1.0 Gram Daily
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 09/04/2002 **Stopped:** 30/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase Troponin				Ck - 2812. Troponin - 2.4.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176340 **Seq:** 1 **Gender:** M
Reported: 17/06/2002 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 29/05/2002 **DOB:** 18/12/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bronchitis			
Chills			
Hyperhidrosis			
Neutropenia			
Pyrexia			
Tachycardia			
Tremor			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
100.0 Milligram Daily Oral
Batch: **Started:** 19/05/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Neutrophils		01/06/2004	1.50	
17/12/2002	White blood cells		01/06/2004	3.48	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176341 **Seq:** 1 **Gender:** M
Reported: 17/06/2002 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 28/03/2002 **DOB:** 28/12/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerking.	

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 375.0 Milligram Daily Oral
Batch: **Started:** 08/03/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electroencephalography				13/06/02 - eeg - diffuse slow wave, non specific, no focal epileptic feature.
	Serum drug level		03/04/2002	480	03/04/02 norclozapine level was 100. clozapine levels as follow.
	Serum drug level		17/04/2002	600	03/04/02 norclozapine level was 100. clozapine levels as follow.

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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176341 **Seq:** 1 **Gender:** M
Reported: 17/06/2002 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 28/03/2002 **DOB:** 28/12/1973
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
Tablet	375.0 Milligram	Daily	Oral	
Batch:	**Started:** 08/03/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		15/05/2002	650	03/04/02 norclozapine level was 100. clozapine levels as follow.
	Serum drug level		29/05/2002	730	03/04/02 norclozapine level was 100. clozapine levels as follow.
	Serum drug level		19/06/2002	560	03/04/02 norclozapine level was 100. clozapine levels as follow.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176342 **Seq:** 1 **Gender:** F
Reported: 17/06/2002 **Weight:**
Hospitalisation: **Age:** 17
Onset Date: 29/05/2002 **DOB:** 21/02/1985
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Heart rate was 160 beats/min.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 24/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Echocardiography was normal. halter monitor results showed intermittent tachycardia.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176343 **Seq:** 1
Reported: 17/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/05/2002
Outcome: Recovered

Gender: M
Weight:
Age: 31
DOB: 25/01/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood pressure fluctuation Blood creatine phosphokinase incr Electrocardiogram abnormal Neutropenia Tachycardia		Unstable blood pressure	Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 100.0 Milligram Daily Oral

Batch: **Started:** 14/05/2002 **Stopped:** 28/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase		28/05/2002	264	
	Neutrophils		20/06/2002	1.44	

Additional Information:

The reporter said that the patient was actually hospitalised sometime ago, due to his mental mood decreasing and not as a result of taking clozaril. other reaction: autonomic nervous system imbalance (not specified).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176344 **Seq:** 1
Reported: 17/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 22/05/2002
Outcome: Unknown

Gender: M
Weight:
Age: 26
DOB: 14/05/1976
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chills Influenza like illness Pyrexia			Patient was hospitalised. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 28/04/2002 **Stopped:** 28/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date for clozaril is not necessarily accurate but indicates the drug was stopped sometime in the month. clozaril was recommenced on 24.5.02, with a daily dose of 12.5mg.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176489 **Seq:** 1 **Gender:** M
Reported: 21/06/2002 **Weight:** 80.00
Hospitalisation: **Age:** 64
Onset Date: 18/09/2001 **DOB:** 27/02/1937
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		Distressed.	
Salivary hypersecretion		Dribbling.	
Pyrexia		Temp 38.7c.	
Fatigue			
Neuroleptic malignant syndrome	Life threatening		Dantrolene, bromocriptine, cefotaxime.
Respiratory disorder			

Medicine Details:

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

CLOZAPINE (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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176499 **Seq:** 1
Reported: 21/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 07/05/2002
Outcome: Unknown

Gender: M
Weight:
Age: 32
DOB: 11/05/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness Hyperhidrosis Nausea Orthostatic hypotension Pyrexia			Patient required hospitalisation and was treated with iv fluids. ceased clopine.

Medicine Details:

NITRAZEPAM (Other drug) **Reason:** Specific disorders of sleep
Tablet 2.0 Dose Unspecified As necessary Oral
Batch: **Started:** 02/04/2002 **Stopped:**

CHLORPROMAZINE HYDROCHLORIDE (Other drug) **Reason:** Unspecified psychosis
100.0 Milligram As necessary
Batch: **Started:** 02/04/2002 **Stopped:**

DIAZEPAM (Other drug) **Reason:** Otr spec symp psychopathol nec
10.0 Milligram As necessary
Batch: **Started:** 02/04/2002 **Stopped:**

CLOPINE (Suspected) **Reason:**
Tablet 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 09/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176579 **Seq:** 1 **Gender:** M
Reported: 24/06/2002 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 28/05/2002 **DOB:** 03/02/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia		Possible pneumonia.	Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 06/05/2002 **Stopped:** 31/05/2002

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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176605 **Seq:** 1
Reported: 17/05/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/03/2002
Outcome: Recovered

Gender: F
Weight:
Age: 33
DOB: 03/03/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea		Severe nausea	
Vomiting		Severe vomiting	Patient was admitted to hospital. pump cotrolled analgesia and a drip. clozaril was ceased.
Peptic ulcer			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 01/01/1998 **Stopped:** 21/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date is not accurate but indicates that the drug was started sometime in the year. during the past 4 years, the patient had at times received clozaril 1200mg/day. the onset date is not necessarily accurate but indicates onset sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176606 **Seq:** 1 **Gender:** F
Reported: 17/05/2002 **Weight:**
Hospitalisation: **Age:** 45
Onset Date: 22/04/2002 **DOB:** 14/04/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
C-reactive protein increased Eosinophilia Leukocytosis Pyrexia Tachycardia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 16/04/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils				Eosinophils 0.93 (normal upper limit 0.4)
	Neutrophils		05/04/2002	7.8	
	Neutrophils		22/04/2002	10.42	
	Neutrophils		24/04/2002	10.97	
	Protein				C-reactive protein 136 and is now slowly decreasing.
	White blood cells		05/04/2002	10.9	
	White blood cells		22/04/2002	13.50	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176606 **Seq:** 1 **Gender:** F
Reported: 17/05/2002 **Weight:**
Hospitalisation: **Age:** 45
Onset Date: 22/04/2002 **DOB:** 14/04/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily	Oral	
Batch:	**Started:** 16/04/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		24/04/2002	13.70	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176618 **Seq:** 1 **Gender:** M
Reported: 24/06/2002 **Weight:**
Hospitalisation: **Age:** 18
Onset Date: 28/05/2002 **DOB:** 27/07/1983
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain			
Chest pain			
Chills			
Lipase increased			
Pancreatitis			Clozaril discontinued.
Vomiting			

Medicine Details:

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

NICOTINE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:** 10/05/2002

OLANZAPINE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:** 17/05/2002

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 01/05/2002 **Stopped:** 21/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Amylase		17/05/2002	NORMAL	
	lipase	30 - 290	17/05/2002	2307	

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176620 **Seq:** 1 **Gender:** M
Reported: 24/06/2002 **Weight:**
Hospitalisation: **Age:** 19
Onset Date: 31/05/2002 **DOB:** 02/03/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Clozaril ceased. given granulocyte colony stimulating factor g-csf.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 275.0 Milligram Daily Oral

Batch: **Started:** 19/03/2002 **Stopped:** 31/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		27/05/2002	1.80	
	Neutrophils		31/05/2002	0.60	
	Neutrophils		25/06/2002	4.60	
	Neutrophils		04/06/2002	18.60	
	White blood cells		27/05/2002	4.60	
	White blood cells		31/05/2002	3.70	
	White blood cells		04/06/2002	23.20	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176620 **Seq:** 1 **Gender:** M
Reported: 24/06/2002 **Weight:**
Hospitalisation: **Age:** 19
Onset Date: 31/05/2002 **DOB:** 02/03/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	275.0 Milligram	Daily	Oral
Batch:	**Started:** 19/03/2002	**Stopped:**	31/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		25/06/2002	6.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176647 **Seq:** 1
Reported: 26/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 07/06/2002
Outcome: Recovered

Gender: F
Weight:
Age: 26
DOB: 13/10/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Patient was hospitalised. treated with granulocyte colony stimulating factor.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		03/06/2002	1.80	
	Neutrophils		05/06/2002	1.10	
	Neutrophils		06/06/2002	0.80	
	Neutrophils		07/06/2002	0.40	
	Neutrophils		11/06/2002	6.00	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176843 **Seq:** 1 **Gender:** F
Reported: 04/07/2002 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 02/01/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Ceased clozaril.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 10/03/1997 **Stopped:** 29/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms 5 years after commencing clozaril. report number 177150 is a duplicate of this report.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176844 **Seq:** 1
Reported: 04/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/06/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 45
DOB: 13/03/1957
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia Coordination abnormal Extrasystoles Malaise Somnolence Tachycardia			Patient was hospitalised, ceased clozaril.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 12/06/2002 **Stopped:** 13/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176845 **Seq:** 1 **Gender:** M
Reported: 04/07/2002 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 28/06/2002 **DOB:** 06/03/1982
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrioventricular block		Atrioventricular block first degree.	Clozaril was discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 07/01/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				7/1/02. in june 2002, he developed "first degree block". electrocardiogram which was performed prior to clozaril start, showed long qrs interval.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. 177316 is a duplicate of 176845.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176889 **Seq:** 1
Reported: 08/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/10/2001
Outcome: Recovered with sequelae

Gender: F
Weight: 86.00
Age: 16
DOB: 16/04/1985
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia Urinary incontinence		Persistent pneumonia - urtis.	Date of recovery 12/2001. patient hospitalised. clozapine ceased. given pneumonia injection.

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:** Manic-depression psycho,manic
1.2 Gram Daily
Batch: **Started:** **Stopped:**

CLOZAPINE (Suspected) **Reason:** Unspecified psychosis
400.0 Milligram Daily
Batch: **Started:** 01/08/2001 **Stopped:** 26/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessariy accurate but indicates onset sometime in the month. the dose start date for the drugs clozapine and valproate are not necessarily accurate but indicate the drugs were started sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176919 **Seq:** 1 **Gender:** M
Reported: 04/07/2002 **Weight:**
Hospitalisation: **Age:** 46
Onset Date: 29/04/2002 **DOB:** 10/11/1955
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 23/01/1995 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology				The white blood cell count had increased from 6.6 to 14.5 and the neutrophil count has climbed from 5.11 to 12.87.the eosinophil count had remained stable.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176967 **Seq:** 1 **Gender:** M
Reported: 08/07/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 28/01/2002 **DOB:** 19/02/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Flushing Tachycardia			Patient was treated with inderal (propranolol hydrochloride).

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 1.6 Gram Daily Oral
Batch: **Started:** 28/12/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				The electrocardiogram showed sinus tachycardia at 120 beats per minute. the t-waves were flattened - biphasic or invented in leads 2,3 and vf+v5. to v6 non specific st-t changes. the conclusion was marked sinus tachycardia.
	Neutrophils		13/12/2000	9X10E9/L	
	Neutrophils		07/06/2002	9X10E9/L	
	White blood cells		13/12/2000	14.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176967 **Seq:** 1 **Gender:** M
Reported: 08/07/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 28/01/2002 **DOB:** 19/02/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:**	
Tablet	1.6 Gram	Daily	Oral	
Batch:	**Started:** 28/12/2001		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		07/06/2002	14.8	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176968 **Seq:** 1 **Gender:** F
Reported: 08/07/2002 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: **DOB:** 23/06/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 26/02/1997 **Stopped:** 28/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date is not necessarily accurate but indicates the drug was stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176995 **Seq:** 1
Reported: 10/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/06/2002
Outcome: Recovered

Gender: M
Weight:
Age: 32
DOB: 30/01/1970
Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Tachycardia			Given atenolol and clonidine. admitted to hospital.

Medicine Details:

LARGACTIL (Other drug) **Reason:** Unspecified schizophrenia
Oral application 600.0 Milligram As necessary Oral
Batch: **Started:** 06/06/2002 **Stopped:** CONTIN

CATAPRES (Other drug) **Reason:** Essential benign hypertension
Oral application 150.0 Microgram As necessary Oral
Batch: **Started:** 06/06/2002 **Stopped:** 26/06/2002

NOTEN (Other drug) **Reason:** Essential benign hypertension
100.0 Milligram Daily
Batch: **Started:** 06/06/2002 **Stopped:** 26/06/2002

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug positive rechallenged. clozapine was rechallenged causing the same reaction to occur.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 176996 **Seq:** 1
Reported: 10/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 22/05/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 20
DOB: 24/08/1981
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia		Atypical pneumonia	
Pyrexia		Temperature 40c.	
Diarrhoea			
Multi-organ failure			
Nausea			Patient put on respirator and given maxolon. admitted to hospital (icu).
Vomiting			

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 150.0 Milligram Daily Oral
Batch: **Started:** 08/05/2002 **Stopped:** 24/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chest X-ray				Chest x ray revealed evidence of pneumonia.
	Creatine				Creatinine kinase = peak of 380.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177063 **Seq:** 1 **Gender:** M
Reported: 12/07/2002 **Weight:** 65.00
Hospitalisation: **Age:** 19
Onset Date: 03/06/2002 **DOB:** 27/12/1982
Outcome: Unknown **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal		T-wave changes non specific.	Required a visit to doctor.

Medicine Details:

VALIUM (Other drug) **Reason:** Unspecified schizophrenia
5.0 Milligram As necessary
Batch: **Started:** 07/05/2002 **Stopped:**

ZYPREXA (Other drug) **Reason:** Unspecified schizophrenia
10.0 Milligram Daily
Batch: **Started:** **Stopped:** 05/06/2002

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
450.0 Milligram Daily
Batch: **Started:** 20/05/2002 **Stopped:** 04/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177131 **Seq:** 1
Reported: 08/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 18/06/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 29
DOB: 15/11/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr			
Eosinophilia			
Lymphopenia			
Pyrexia			
Tachycardia			Patient hospitalised.
Troponin increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

225.0 Milligram Daily Oral

Batch: **Started:** 04/06/2002 **Stopped:** 18/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Creatine phosphokinase	30 - 200 IU/L	26/02/2004	493	
17/12/2002	Creatine phosphokinase	30 - 200 IU/L	26/02/2004	425	
17/12/2002	Electrocardiograph				
17/12/2002	Eosinophils				
17/12/2002	Lymphocytes	1.2 - 4.0	26/02/2004	0.6	
17/12/2002	Troponin				
17/12/2002	White blood cells		26/02/2004	9.7X10E9/L	

Additional Information:

Myocarditis suspected.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177132 **Seq:** 1 **Gender:** F
Reported: 27/06/2002 **Weight:**
Hospitalisation: **Age:** 16
Onset Date: 28/05/2002 **DOB:** 21/08/1985
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Blood creatine phosphokinase incr Pyrexia Troponin increased	Life threatening	Life thratening.	

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 13/05/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiololgy				Normal electrocardiogram and cardiac echocardiography.
	Troponin		29/05/2002	0.2 UG/L	
	White blood cells		29/05/2002	10.80	

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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177148 **Seq:** 1 **Gender:** F
Reported: 11/07/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 28/05/2002 **DOB:** 23/06/1961
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cholelithiasis Hepatitis Jaundice			Clozaril was descontinued.

Medicine Details:

RISPERIDONE (Other drug) **Reason:**
0.0
Batch: **Started:** 08/01/2002 **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 26/02/1997 **Stopped:** 28/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	<55	01/01/2002	60	
	ALT = SGPT	<55	28/05/2002	538	
	SAP = ALP	0-120	01/01/2002	256	
	SAP = ALP	0-120	28/05/2002	684	

Additional Information:

The dose stop date is not necessarily accurate but indicates the clozaril was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177165 **Seq:** 1 **Gender:** F
Reported: 15/07/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: **DOB:** 01/12/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy			Clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 375.0 Milligram Daily Oral
Batch: **Started:** 07/03/2000 **Stopped:** 27/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177166 **Seq:** 1 **Gender:** M
Reported: 15/07/2002 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 06/07/2002 **DOB:** 30/01/1970
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Tachycardia			

Medicine Details:

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

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

LARGACTIL (Other drug) **Reason:**
Oral application 100.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 01/07/1997 **Stopped:** 27/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177168 **Seq:** 1
Reported: 15/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 17/04/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 22
DOB: 24/06/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Sinus tachycardia	Patient was hospitalisd. dose reduction of clozaril to 350mg daily and the discontinuation of oxybutynin. treated with propranolol hcl.
Dyspnoea Nausea Vomiting		Some pain when patient breathed.	

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 2.0 Gram Daily Oral
Batch: **Started:** 30/10/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph Other data				Echocardiogram showed no evidence of myocarditis or cardiomyopathy. electrocardiogram showed sinus tachycardia. Computed tomography pulmonary angiogram was normal.

Additional Information:

The patient was investigated for mycarditis but the condition was excluded. had developped similar symptoms unrelated to drug therapy.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177236 **Seq:** 1 **Gender:** M
Reported: 18/07/2002 **Weight:**
Hospitalisation: **Age:** 61
Onset Date: 21/03/2002 **DOB:** 29/08/1940
Outcome: Unrelated death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aspiration Cerebrovascular disorder Pneumonia			Patient died on 9/6/02.

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 29/09/1995 **Stopped:** 01/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		27/05/2002	16.50	
	White blood cells		27/05/2002	22.50	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177237 **Seq:** 1
Reported: 19/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/06/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 33
DOB: 22/03/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Neutropenia			Ceased clozaril. patient hospitalised.

Medicine Details:

ZANTAC (Other drug)			**Reason:**	Other diseases of esophagus	
Oral application	300.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
THIAMINE (Other drug)			**Reason:**		
Oral application	100.0	Milligram	Daily	Oral	
Batch:	**Started:** 27/06/2002			**Stopped:**	
MONOPLUS 20/12.5 (Other drug)			**Reason:**	Essential benign hypertension	
Oral application	1.0	Dose Unspecified	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
GLIPIZIDE (Other drug)			**Reason:**	Diabetes mellitus	
Oral application	5.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		27/05/2002	9.40	
	Neutrophils		24/06/2002	0.90	
	Neutrophils		25/06/2002	0.8	
	Neutrophils		26/06/2002	0.5	
	Neutrophils		27/06/2002	0.5	
	White blood cells		27/05/2002	11.20	
	White blood cells		24/06/2002	2.90	

Additional Information:

Not thought to be related to clozaril, rather the wound was the cause. report 176716 is a duplicate of this report.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177237 **Seq:** 1
Reported: 19/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/06/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 33
DOB: 22/03/1969
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Schizophrenia	
Tablet	325.0 Milligram		Daily	Oral
Batch:	**Started:** 15/09/1994		**Stopped:** 24/06/2002	
VANCOMYCIN HYDROCHLORIDE (Suspected)			**Reason:** Bacterial disease nec	
Injection	2.0 Gram		Daily	Intravenous
Batch:	**Started:** 03/06/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Additional Information:

Not thought to be related to clozaril, rather the wound was the cause. report 176716 is a duplicate of this report.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177248 **Seq:** 1 **Gender:** U
Reported: 19/07/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				High c-reactive protein levels.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177289 **Seq:** 1
Reported: 22/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 22/07/2002
Outcome: Unknown

Gender: M
Weight:
Age: 26Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177317 **Seq:** 1
Reported: 19/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 01/07/2002
Outcome: Unknown

Gender: F
Weight:
Age: 20
DOB: 13/07/1981
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Eosinophilia		With a heart rate of 100-120 bpm.	Nicotine patches were discontinued.

Medicine Details:

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

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

NICOTINE TRANSDERMAL PATCH (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 18/06/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils		29/05/2002	0.78	
	Eosinophils		03/07/2002	1.13	
	Neutrophils		03/07/2002	6.8	
	White blood cells		03/07/2002	10.30	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177318 **Seq:** 1 **Gender:** F
Reported: 19/07/2002 **Weight:**
Hospitalisation: **Age:** 17
Onset Date: 28/06/2002 **DOB:** 16/04/1985
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection in an immunocompromise Drug ineffective Salivary hypersecretion Urinary incontinence Weight increased		Frequent lung, middle ear & urinary tract infec.	

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 13/11/2001 **Stopped:** 26/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		05/06/2002	4.60	
	White blood cells		05/06/2002	7.1	

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. history of rare syndrome with mild mental retardation, premature greying and e ndocrinopathy (thyroid and diabetes).

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177346 **Seq:** 1 **Gender:** M
Reported: 19/07/2002 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 02/07/2002 **DOB:** 07/08/1968
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Accidental exposure Feeling abnormal Malaise			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 150.0 Milligram 1 time Oral

Batch: **Started:** 02/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/07/2002	Electrocardiograph				

Additional Information:

On 02/07/2002 this patient had taken another patient's clozaril, 150 to 600mg over 2 days. He was found sitting, staring into space and feeling very ill.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177361 **Seq:** 1
Reported: 22/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/06/2002
Outcome: Unknown

Gender: F
Weight:
Age: 34
DOB: 14/03/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Drug ineffective Psychotic disorder		Overdose of clozaril 2000mg	Patient was hospitalised and clozaril was increased to 475 mg daily.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 31/05/1994 **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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177362 **Seq:** 1 **Gender:** M
Reported: 22/07/2002 **Weight:**
Hospitalisation: **Age:** 25
Onset Date: 03/07/2002 **DOB:** 07/06/1977
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis Troponin increased			Clozaril was ceased.

Medicine Details:

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

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 30/08/1994 **Stopped:** 19/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin				Raised troponin on 03 july 2002.

Additional Information:

178724 is a duplicate of 177362

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177363 **Seq:** 1
Reported: 22/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/06/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 35
DOB: 05/07/1966
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Junctional tachycardia	
Troponin increased		Possible mild myocardial injury.	Temporary discontinuation of clozaril and hospitalisation.
Consciousness fluctuating			

Medicine Details:

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

Tablet 150.0 Milligram Daily Oral

Batch: **Started:** 25/06/1997 **Stopped:** 02/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin				Increased troponin june 2002.

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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177364 **Seq:** 1 **Gender:** U
Reported: 22/07/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 0.0 Oral
Batch: **Started:** 01/01/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin				Elevated troponin levels on july 2002.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177455 **Seq:** 1
Reported: 19/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/04/2002
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 46
DOB: 15/02/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Brain neoplasm malignant Coma Hallucination Shock		In the parietal lobe region.	Patient was hospitalised, ceased clozaril and unwent a cat scan. patient died 18/5/02.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 01/01/1995 **Stopped:** 28/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Cat scan revealed a growth in the parietal lobe region.

Additional Information:

The dose start date is not necessarily accurate but indicates clozaril was started sometime in the year. history of hydatid cysts. 175616 and 177315 are duplicates of 177455.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177461 **Seq:** 1 **Gender:** M
Reported: 19/07/2002 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 08/07/2002 **DOB:** 06/03/1975
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Aspiration Suicide attempt		Overdose ? multiple drugs.	Date of death 8/7/02 -autopsy performed.

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 22/05/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking metazapine.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177505 **Seq:** 1
Reported: 29/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 18/07/2002
Outcome: Recovered

Gender: M
Weight: 85.00
Age: 24
DOB: 01/10/1977
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion Coordination abnormal Confusional state Fatigue Somnolence Tachycardia		Drooling saliva. Staggering	Patient was hospitalised. date of recovery: 19/7/02.

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Other drug) **Reason:**
300.0 Milligram Fortnightly
Batch: **Started:** **Stopped:** 25/06/2002

RISPERDAL (Other drug) **Reason:**
3.0 Milligram Daily
Batch: **Started:** 16/05/2002 **Stopped:** 27/05/2002

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
0.0
Batch: **Started:** 04/07/2002 **Stopped:** 18/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177525 **Seq:** 1
Reported: 29/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 25/06/2002
Outcome: Recovered

Gender: M
Weight:
Age: 28
DOB: 28/01/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged Confusional state Viral infection		Prolonged qt and a possible arrhythmia.	Clozaril ceased. hospital admission

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 14/12/2000 **Stopped:** 26/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had an intercurrent viral illness at the time.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177531 **Seq:** 1 **Gender:** M
Reported: 29/07/2002 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 28/06/2002 **DOB:** 18/12/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Sinus tachycardia.	Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 14/05/2002 **Stopped:** 17/06/2002

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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177556 **Seq:** 1
Reported: 31/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 11/07/2002
Outcome: Unknown

Gender: F
Weight:
Age: 70
DOB: 19/03/1932
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Patient was hospitalised in the icu.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 11/03/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of transient ischemic attack.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177558 **Seq:** 1
Reported: 31/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/07/2002
Outcome: Unknown

Gender: F
Weight:
Age: 32
DOB: 20/10/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Anaemia Lymphopenia Thrombocytopenia			Patient was hospitalised. reaction resolving.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** 16/11/2001 **Stopped:** 28/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology		14/07/2002	0.34	Hematocrin cell volume
	Haematology		14/07/2002	0.29	Hematocrin cell volume
	Haematology		16/07/2002	0.29	Hematocrin cell volume
	Lymphocytes		14/07/2002	0.3	
	Neutrophils		16/11/2001	4.06	
	Neutrophils		16/07/2002	0.00	
	Neutrophils		17/07/2002	0.00	

Additional Information:

The dose stop date is not necessarily accurate but indicates clozaril was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177558 **Seq:** 1
Reported: 31/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/07/2002
Outcome: Unknown

Gender: F
Weight:
Age: 32
DOB: 20/10/1969
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet	600.0 Milligram	Daily	Oral
Batch:	**Started:** 16/11/2001	**Stopped:**	28/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		14/07/2002	0.00	
	Neutrophils		18/07/2002	0.10	
	Neutrophils		20/07/2002	0.10	
	Neutrophils		22/07/2002	2.03	
	Neutrophils		23/07/2002	6.30	
	Neutrophils		21/07/2002	0.50	
	Neutrophils		19/07/2002	0.00	

Additional Information:

The dose stop date is not necessarily accurate but indicates clozaril was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177558 **Seq:** 1
Reported: 31/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/07/2002
Outcome: Unknown

Gender: F
Weight:
Age: 32
DOB: 20/10/1969
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet	600.0 Milligram	Daily	Oral
Batch:	**Started:** 16/11/2001	**Stopped:**	28/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets		14/07/2002	137	
	Platelets		14/07/2002	114	
	White blood cells		16/11/2001	5.54	
	White blood cells		14/07/2002	0.40	
	White blood cells		16/07/2002	0.50	
	White blood cells		17/07/2002	0.70	
	White blood cells		18/07/2002	1.10	

Additional Information:

The dose stop date is not necessarily accurate but indicates clozaril was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177558 **Seq:** 1
Reported: 31/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/07/2002
Outcome: Unknown

Gender: F
Weight:
Age: 32
DOB: 20/10/1969
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** 16/11/2001 **Stopped:** 28/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		19/07/2002	1.30	
	White blood cells		20/07/2002	1.50	
	White blood cells		21/07/2002	2.90	
	White blood cells		22/07/2002	6.00	
	White blood cells		23/07/2002	13.50	

Additional Information:

The dose stop date is not necessarily accurate but indicates clozaril was stopped sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177559 **Seq:** 1
Reported: 31/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 11/07/2002
Outcome: Recovered

Gender: M
Weight:
Age: 45
DOB: 01/06/1957
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Clozaril was ceased. was scheduled to be given filgrastim.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 175.0 Milligram Daily Oral

Batch: **Started:** 17/05/2002 **Stopped:** 03/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		17/05/2002	3.5	
	Neutrophils		03/07/2002	1.60	
	Neutrophils		16/07/2002	3.00	
	Neutrophils		11/07/2002	0.00	
	White blood cells		17/05/2002	5	
	White blood cells		05/07/2002	2.80	
	White blood cells		12/07/2002	2.30	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177559 **Seq:** 1
Reported: 31/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 11/07/2002
Outcome: Recovered

Gender: M
Weight:
Age: 45
DOB: 01/06/1957
Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Schizophrenia	
Tablet	175.0 Milligram		Daily	Oral
Batch:	**Started:** 17/05/2002		**Stopped:** 03/07/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		15/07/2002	5.50	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177625 **Seq:** 1
Reported: 02/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 18/07/2002
Outcome: Recovered

Gender: M
Weight:
Age: 49
DOB: 23/03/1953
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysarthria Accidental overdose Coordination abnormal Dizziness Medication error		Slurred speech.	Admitted to hospital.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 18/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The support worker gave the patient 200mg instead of 12.5mg on 18/07/2002.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177824 **Seq:** 1
Reported: 21/06/2002
Hospitalisation: Admitted to hospital
Onset Date: 01/06/2002
Outcome: Unknown

Gender: M
Weight:
Age: 34
DOB: 28/10/1967
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Infection		Chest infection	
Pyrexia		Chest infection.	Patient hospitalised.
Tremor			

Medicine Details:

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

BENZTROPINE MESYLATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 20/05/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The concomitant medication of olanzapine is currently being titrated down.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177838 **Seq:** 1 **Gender:** M
Reported: 07/08/2002 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: **DOB:** 29/11/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Clopine ceased.

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 09/05/2002 **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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177897 **Seq:** 1 **Gender:** M
Reported: 07/08/2002 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 20/07/2002 **DOB:** 20/08/1969
Outcome: Death **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sudden death		Sudden, unexplained death.	

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 950.0 Milligram Daily Oral
Batch: **Started:** 29/05/2001 **Stopped:** 20/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177900 **Seq:** 1 **Gender:** F
Reported: 07/06/2002 **Weight:**
Hospitalisation: **Age:** 26
Onset Date: 26/04/2002 **DOB:** 17/12/1975
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Clozaril ceased.

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug) **Reason:**
225.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 12/04/2002 **Stopped:** 26/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		26/04/2002	67	
	ALT = SGPT		27/04/2002	73	
	ALT = SGPT		30/04/2002	49	
	ALT = SGPT		29/04/2002	47	
	AST = SGOT		26/04/2002	45	
	AST = SGOT		30/04/2002	38	
	AST = SGOT		27/04/2002	58	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177900 **Seq:** 1
Reported: 07/06/2002
Hospitalisation:
Onset Date: 26/04/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 26
DOB: 17/12/1975
Causality: Causality probable

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)			**Reason:**	
	225.0 Milligram		Daily	
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
Tablet	300.0 Milligram		Daily	Oral
Batch:	**Started:** 12/04/2002		**Stopped:**	26/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT = SGOTD		26/04/2002	338	
	GGT = SGGT = SGOTD		27/04/2002	607	
	GGT = SGGT = SGOTD		29/04/2002	467	
	GGT = SGGT = SGOTD		07/05/2002	210	
	GGT = SGGT = SGOTD		30/04/2002	468	
	SAP = ALP		26/04/2002	193	
	SAP = ALP		27/04/2002	286	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177900 **Seq:** 1
Reported: 07/06/2002
Hospitalisation:
Onset Date: 26/04/2002
Outcome: Not yet recovered

Gender: F
Weight:
Age: 26
DOB: 17/12/1975
Causality: Causality probable

Reaction Details:

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)			**Reason:**	
	225.0 Milligram		Daily	
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
Tablet	300.0 Milligram		Daily	Oral
Batch:	**Started:** 12/04/2002		**Stopped:**	26/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		29/04/2002	233	
	SAP = ALP		30/04/2002	232	
	SAP = ALP		07/05/2002	129	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177930 **Seq:** 1
Reported: 04/07/2002
Hospitalisation: Admitted to hospital
Onset Date: 19/04/2002
Outcome: Recovered

Gender: M
Weight:
Age: 58
DOB: 20/07/1943
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Pharyngitis Viral infection			Clozaril ceased.

Medicine Details:

OLANZAPINE (Other drug) **Reason:**

0.0

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 650.0 Milligram Daily Oral

Batch: **Started:** 15/09/1995 **Stopped:** 15/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		30/04/2002	2.40	
	Neutrophils		15/05/2002	1.8	
	Neutrophils		16/05/2002	2.10	
	White blood cells		30/04/2002	3.60	
	White blood cells		15/05/2002	2.8	
	White blood cells		16/05/2002	3.4	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177945 **Seq:** 1
Reported: 08/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 15/07/2002
Outcome: Unknown

Gender: M
Weight:
Age: 30
DOB: 10/07/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Patient was hospitalised. treated with sodium valproate 500mg bd.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 600.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electroencephalography				Eeg was consistent with frontal lobe epilepsy. a ct head was normal.

Additional Information:

Patient had never fitted before.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177949 **Seq:** 1
Reported: 08/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/07/2002
Outcome: Recovered

Gender: M
Weight:
Age: 24
DOB: 01/10/1977
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Hyperhidrosis Neuroleptic malignant syndrome Photophobia Pyrexia Salivary hypersecretion Tachycardia			Patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 05/07/2002 **Stopped:** 18/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				July 2002 - cpk elevated.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 177998 **Seq:** 1 **Gender:** F
Reported: 12/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 10/04/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Malaise Nausea Tachycardia Vomiting			Clozapine reduced 150mg mane, 200mg nocte.

Medicine Details:

OXYBUTYNIN HYDROCHLORIDE (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 17/04/2002

CLOZAPINE (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** S TERM **Stopped:** 17/04/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178093 **Seq:** 1 **Gender:** M
Reported: 15/08/2002 **Weight:** 106.00
Hospitalisation: **Age:** 39
Onset Date: 30/05/2002 **DOB:** 17/11/1962
Outcome: Recovered **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash Constipation Urinary incontinence		Rash on shoulder.	Patient required a visit to doctor. date of recovery: 24/6/02. ceased clozapine.

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 09/08/2001 **Stopped:** 24/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178134 **Seq:** 1 **Gender:** M
Reported: 16/08/2002 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 17/02/2002 **DOB:** 04/01/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly Neutropenia			Patient referred to a haematologist and cardiologist.

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 21/12/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils Radiololgy		17/02/2002	1.1	 X-ray revealing an enlarged heart.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178152 **Seq:** 1 **Gender:** M
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 01/01/2002 **DOB:** 15/11/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		106 bpm	
Cardiomegaly	Required Visit to Doctor	Moderate septal hypertrophy.	
Hyperglycaemia			

Medicine Details:

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

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

ZOLOFT (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:** CONTIN

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 22/02/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph Serum glucose		 27/02/2000	 9.4MMOL/L	31 may 2002: echocardiography showed moderate septal hypertrophy. 09 jan 2002: ecg showed sinus tachycardia (106 bpm) and non-specific anterolat eral t abnormalities.

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178153 **Seq:** 1 **Gender:** U
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 01/01/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aortic stenosis Cardiomegaly			

Medicine Details:

CLOZARIL (Suspected) **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 accurate but indicates onset sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178154 **Seq:** 1 **Gender:** M
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 55
Onset Date: 03/06/2002 **DOB:** 08/11/1946
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly	Required Specialist Consultation		

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 25/05/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				10 apr 2002: echocardiography showed mild concentric left ventricular hypertrophy, diastolic dysfunction.

Additional Information:

The date of onset is not accurate but indicates onset soemtime in the year. mild concentric left ventricular hypertrophy and diastolic dysfunction.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178155 **Seq:** 1 **Gender:** M
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 01/01/2002 **DOB:** 10/04/1953
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly	Required Specialist Consultation	Moderate concentric left ventricular hyperstrophy.	

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 18/01/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				31 may 2002: echocardiography showed moderate concentric left ventricular hypertrophy. 09/1/2002 echocardiogram normal.

Additional Information:

The date of onset is not accurate but indicates onset sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178156 **Seq:** 1 **Gender:** M
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: 09/01/2002 **DOB:** 05/01/1959
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		105 bpm	
Cardiomegaly		Dilatation ventricular.	
Cardiomegaly		Right atrial enlargement.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				31 may 2002: echocardiography showed borderline septal hypertrophy and mild right ventricular enlargement on mode measurement.

Additional Information:

Borderline septal hypertrophy and mild right ventricular enlargement.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178160 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 09/01/2002 **DOB:** 01/02/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly	Required Specialist Consultation	Mild septal hypertrophy; left atrial enlargement	
Tachycardia		Sinus tachycardia 123	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 16/02/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				26 mar 2002: echocardiography showed mild septal hypertrophy. no evidence of drug induced myocarditis.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178182 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 29/07/2002 **DOB:** 02/05/1966
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 75.0 Milligram Daily Oral
Batch: **Started:** 09/12/1996 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		03/06/2002	75	
	Neutrophils		01/07/2002	3.6	
	Neutrophils		29/07/2002	0.6	
	Neutrophils		03/08/2002	2.6	
	Neutrophils		30/07/2002	0.5	
	White blood cells		03/06/2002	7.2	
	White blood cells		01/07/2002	6.3	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178182 **Seq:** 1 **Gender:** F
Reported: 19/08/2002 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 29/07/2002 **DOB:** 02/05/1966
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)			**Reason:**	
Tablet	75.0 Milligram	Daily	Oral	
Batch:	**Started:** 09/12/1996		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		29/07/2002	2.6	
	White blood cells		30/07/2002	2.7	
	White blood cells		03/08/2002	6.0	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178352 **Seq:** 1 **Gender:** M
Reported: 22/08/2002 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 20/06/2002 **DOB:** 04/03/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state	Life threatening		Clopine ceased.
Convulsion	Life threatening		
Neurosis			

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 31/08/2001 **Stopped:** 19/06/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of drug dependance: benzodiazepine, amphetamines, heroin and marijuana patients underlying psychiatric illness and drug abuse are more likely causes.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178439 **Seq:** 1 **Gender:** M
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178441 **Seq:** 1
Reported: 23/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2002
Outcome: Recovered

Gender: M
Weight:
Age: 39
DOB: 27/07/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism		Pulmonary embolism 47 wks after commencing therapy	Patient was hospitalised and treated with heparin.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 06/09/2001 **Stopped:** 28/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date is not necessarily accurate but indicates clozaril was stopped sometime in the month.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178442 **Seq:** 1 **Gender:** M
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 28/05/1955
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anaemia		Haematocrit decreased and haemoglobin decreased	
Hepatitis viral			Patient hospitalised. artane ceased.
Leukocytosis			
Pneumonia			
Thrombocytopenia			

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 16/05/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	< 40 U/L	01/10/2002	62	
	AST = SGOT	< 40 U/L	07/10/2002	75	
	GGT = SGGT =	< 50 U/L	01/10/2002	83	
	GGT = SGGT =	< 50 U/L	07/10/2002	70	
	Haemoglobin	135 - 180 G/DL	14/05/2002	136	
	Haemoglobin	135 - 180 G/DL	03/09/2002	134	
	Haemoglobin	135 - 180 G/DL	23/09/2002	105	

Additional Information:

Fluctulating platelet counts and possible immune thrombocytopenia approcimately 8 years and 2.5 months after commencing clozaril (clozapine therapy). onset of reaction 03/09/02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178442 **Seq:** 1 **Gender:** M
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 28/05/1955
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

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

CLOZARIL (Suspected) **Reason:**
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 16/05/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin	135 - 180 G/DL	19/09/2002	103	
	Haemoglobin	135 - 180 G/DL	07/10/2002	115	
	Haemoglobin	135 - 180 G/DL	01/10/2002	111	
	Platelets	140 - 400	24/04/2002	70	
	Platelets	140 - 400	14/05/2002	70	
	Platelets	140 - 400	16/05/2002	65	
	Platelets	140 - 400	11/06/2002	79	

Additional Information:

Fluctulating platelet counts and possible immune thrombocytopenia approcimately 8 years and 2.5 months after commencing clozaril (clozapine therapy). onset of reaction 03/09/02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178442 **Seq:** 1 **Gender:** M
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: **DOB:** 28/05/1955
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

ARTANE (Suspected)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
Tablet	300.0 Milligram	Daily	Oral	
Batch:	**Started:** 16/05/1994		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Platelets	140 - 400	09/07/2002	56	
	Platelets	140 - 400	03/09/2002	58	
	Platelets	140 - 400	19/09/2002	68	
	Platelets	140 - 400	23/09/2002	104	
	Platelets	140 - 400	01/10/2002	104	
	Platelets	140 - 400	07/10/2002	109	

Additional Information:

Fluctulating platelet counts and possible immune thrombocytopenia approcimately 8 years and 2.5 months after commencing clozaril (clozapine therapy). onset of reaction 03/09/02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178443 **Seq:** 1 **Gender:** M
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:** 18
Onset Date: 31/07/2002 **DOB:** 25/10/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis Hepatic function abnormal			Patient was hospitalised and treated with granulocyte colony stimulating factors. ceased clozapine.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 02/05/2002 **Stopped:** 07/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	(5-40)	07/08/2002	51	
	AST = SGOT	(10-50)	07/08/2002	53	
	GGT = SGGT =	(5-60)	07/08/2002	66	
	Neutrophils		02/05/2002	4.3	
	Neutrophils		31/07/2002	1.00	
	Neutrophils		05/08/2002	0.30	
	Neutrophils		07/08/2002	2.40	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178443 **Seq:** 1 **Gender:** M
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:** 18
Onset Date: 31/07/2002 **DOB:** 25/10/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 02/05/2002 **Stopped:** 07/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		02/05/2002	8.2	
	White blood cells		31/07/2002	6.10	
	White blood cells		05/08/2002	9.90	
	White blood cells		07/08/2002	21.70	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178451 **Seq:** 1 **Gender:** F
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 01/08/2002 **DOB:** 29/08/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia		Aches and pains.	
Pyrexia		Raised temperatures.	
Neutropenia		Viral neutropenia.	Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 24/07/1995 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Lymph node biopsy				The patient was bedridden and presented with a typical lymphocytes on pathology slide in august 2002, approximately 7 years after commencing clozaril.
	Neutrophils		24/07/2002	9.4	
	Neutrophils		08/08/2002	1.31	
	White blood cells		24/07/2002	13.3	
	White blood cells		08/08/2002	2.8	

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178452 **Seq:** 1 **Gender:** F
Reported: 23/08/2002 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: 01/08/2002 **DOB:** 16/10/1968
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged Tachycardia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 10/04/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Electrocardiogram was done (unspecified date) and showed evidence of a sinus tachycardia and possible qt prolongation.

Additional Information:

She date of onset is not necessarily accurate but indicates onset sometime in the month. siuns tachycardia (100 beats per minute) and possible qt prolongationin aug 2002, 1 year and 4 months after commencing clozaril (clozapine) therapy. this report is the second of two sequences: 149574 seq 1.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178531 **Seq:** 1 **Gender:** F
Reported: 28/08/2002 **Weight:**
Hospitalisation: **Age:** 45
Onset Date: 28/07/2002 **DOB:** 03/06/1957
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion Pleural effusion			

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 450.0 Milligram Daily Oral
Batch: **Started:** 09/09/1997 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				July 2002 - echo revealed a localised pleural effusion august 2002 - echo indicated that the effusion had become more extensive.
	Other data				Ct scan confirmed a pericardial small effusion (dates of those tests were not provided.
	Radiololgy				A second echo (in aug 2002) which indicated that the effusion has become more extensive.

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the report throught caused by post viral infection.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178534 **Seq:** 1 **Gender:** U
Reported: 28/08/2002 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: 28/07/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Dizziness Electrocardiogram QT prolonged			

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 0.0 Oral
Batch: **Started:** 01/07/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				The patient underwent ecg in july 2002 and the results showed qt prolongation a repeated ecg showed that the qt prolongation had not resolved (two weeks aft er the initial ecg).

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 clozaril was started sometime in the month. report 178533 is a duplicate of this report.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178556 **Seq:** 1
Reported: 29/08/2002
Hospitalisation: Admitted to hospital
Onset Date: 16/07/2002
Outcome: Unknown

Gender: M
Weight:
Age: 25
DOB: 07/05/1977
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Patient was hospitalised.

Medicine Details:

CLONAZEPAM (Other drug)			**Reason:**	
Oral application	1.0 Milligram		Daily	Oral
Batch:	**Started:** 11/07/2002		**Stopped:**	14/07/2002
CLOPINE (Suspected)			**Reason:**	
Tablet	112.0 Milligram		Daily	Oral
Batch:	**Started:** 11/07/2002		**Stopped:**	19/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is an epileptic with a history of drug dependence. clopine therapy commenced on 09/07/02 at a dose of 25mg, daily, orally. the da ily dose was increased to 87.5mg on 11/07/02. treatement with clonazepam 1mg nocte was commenced on 11/07/02, reduced to 0.5mg nocte on 15/07/02 and ceased on 16/07/02. the intention was to gradually reduce clonazepam whilst the cloza pine dose was gradually increased. however, the patient experienced more and m ore petit-mal seizures on 16/07/02 and opted to cease clopine therapy on 19/07/02.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178592 **Seq:** 1
Reported: 04/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 12/08/2002
Outcome: Death, maybe drug

Gender: M
Weight:
Age: 39
DOB: 30/08/1962
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest Cardiomyopathy Hypocalcaemia Hypokalaemia Hyponatraemia Neuroleptic malignant syndrome Pyrexia Shock			Patient died: 16/8/02.

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 16/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Calcium	1.12 - 1.30 MMOL/L	15/08/2002	0.9	
	Creatine [illegible]	30 - 200 IU/L	15/08/2002	1360	
	Potassium	3.5 - 5.5 MMOL/L	15/08/2002	2.9	
	Sodium	135 - 145 MMOL/L	15/08/2002	129	

Additional Information:

Risk factors were: obesity, known aortic valve stenosis. the patient presented to the emergency department, collapsed and could not be resuscitated. the patient died on 16/08/02.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178620 **Seq:** 1 **Gender:** M
Reported: 08/08/2002 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 28/12/2001 **DOB:** 29/05/1969
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Neutropenia			Clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 175.0 Milligram Daily Oral

Batch: **Started:** 15/12/2001 **Stopped:** 01/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		31/12/2001	140	Alt (date unknown) 80 (upper limit normal 45)
	ALT = SGPT		15/06/2002	197	Alt (date unknown) 80 (upper limit normal 45)
	Neutrophils		13/12/2001	3.48	
	Neutrophils		03/06/2002	1.80	

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178630 **Seq:** 1 **Gender:** M
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/06/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure		Cardiac ventricular disorder	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 01/01/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				25% ejection fraction.

Additional Information:

Did not have other signs or symptoms of cardiac failure. the onset date is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates clozaril was started sometime in the year.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178637 **Seq:** 1
Reported: 02/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 05/08/2002
Outcome: Recovered

Gender: F
Weight:
Age: 27
DOB: 28/03/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nightmare		Increased dream intensity	
Constipation			
Dizziness			
Fatigue			Patient was hospitalised, given benzytropine. patient recovered 13/8/02.
Increased appetite			
Nausea			
Salivary hypersecretion			
Tachycardia			

Medicine Details:

QUILONUM SR (Other drug) **Reason:**
1.3 Gram Daily
Batch: **Started:** 17/07/2002 **Stopped:**

CLOZARIL (Suspected) **Reason:** Schizophrenia
125.0 Milligram Daily
Batch: **Started:** 29/07/2002 **Stopped:** 11/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

"breathing difficultes" on quetiapine (senoquel). previous weight gain/increased appetite with olanzapine (zyprexa)

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178637 **Seq:** 1
Reported: 02/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 05/08/2002
Outcome: Recovered

Gender: F
Weight:
Age: 27
DOB: 28/03/1975
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor Visual disturbance	Required Specialist Consultation		

Medicine Details:

QUILONUM SR (Other drug) **Reason:**
1.3 Gram Daily
Batch: **Started:** 17/07/2002 **Stopped:**

CLOZARIL (Suspected) **Reason:** Schizophrenia
125.0 Milligram Daily
Batch: **Started:** 29/07/2002 **Stopped:** 11/08/2002

Laboratory Investigations:

Additional Information:

"breathing difficultes" on quetiapine (senoquel). previous weight gain/increased appetite with olanzapine (zyprexa)

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178642 **Seq:** 1
Reported: 02/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 11/07/2002
Outcome: Unknown

Gender: F
Weight:
Age: 70
DOB: 19/03/1932
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bronchitis Convulsion Hypoxia Leukocytosis			Patient was hospitalised in intensive care unit.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 20.5 Milligram Daily Oral

Batch: **Started:** 11/03/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		11/03/2002	12.3	
	Neutrophils		08/07/2002	12.06	
	Neutrophils		22/07/2002	20.50	
	White blood cells		11/03/2002	16.6	
	White blood cells		08/07/2002	15.50	
	White blood cells		22/07/2002	24.50	

Additional Information:

History of transient ischemic attack(tia). history of chronic airway disease and developed approximately 7 chest infections within a 6 month period.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178659 **Seq:** 1 **Gender:** F
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 19/07/2002 **DOB:** 13/07/1954
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Electroencephalogram abnormal			

Medicine Details:

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

SPAN-K (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 18/09/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Eeg showed seizure activity.

Additional Information:

Patient has a history of seizures but had been well for many years. patient previously expeirenced seizures whilst taking chlorpromazine. 177946 is a duplicate of this report.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178662 **Seq:** 1 **Gender:** F
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: 28/07/2002 **DOB:** 09/11/1959
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram T wave inversio Electrocardiogram abnormal Myocarditis	Life threatening		Clopine ceased.

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 10/08/2001 **Stopped:** 19/07/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Abnormal ecg with inverted t waves in the anterolateral leads.
	Radiololgy				No abnormalitites were detected in a coronary angiogram.

Additional Information:

Patient began treatment with copline on 10 august 2001 and had been increased to 400 mg/daily from 350 mg/daily on the 10 july 2002. 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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178666 **Seq:** 1
Reported: 02/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 09/08/2002
Outcome: Recovered

Gender: F
Weight:
Age: 40
DOB: 04/06/1962
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		High temperature of 38.c	Clozaril discontinued. admitted to hospital and given panadol, iv saline.
Rash		On chest.	
Arthralgia		Wrist pain.	
Anaemia			
Neutropenia			

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 24/07/2002 **Stopped:** 14/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haematology	3.80 - 5.50	14/08/2002	3.53	Packed cell volume (pcv)
	Neutrophils		24/07/2002	3.7	
	Neutrophils		06/08/2002	1.9	
	Neutrophils		13/08/2002	4.2	
	Red blood cells	115 - 165	14/08/2002	105	
	White blood cells		24/07/2002	5.3	
	White blood cells		06/08/2002	3.3	

Additional Information:

Medical history - mental impairment nos.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178666 **Seq:** 1
Reported: 02/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 09/08/2002
Outcome: Recovered

Gender: F
Weight:
Age: 40
DOB: 04/06/1962
Causality: Causality probable

Reaction Details:

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 225.0 Milligram Daily Oral
Batch: **Started:** 24/07/2002 **Stopped:** 14/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		13/08/2002	5.3	
	White blood cells		14/08/2002	3.1	

Additional Information:
Medical history - mental impairment nos.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178678 **Seq:** 1 **Gender:** F
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 29/07/2002 **DOB:** 28/03/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion Somnolence Tachycardia			Clozaril discontinued. patient given benztropine.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 12.5 Milligram Daily Oral

Batch: **Started:** 29/07/2002 **Stopped:** 12/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178679 **Seq:** 1
Reported: 02/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/02/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 47
DOB: 05/01/1955
Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased			Patient hospitalised. clozaril therapy reduced to 400mg/daily.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 500.0 Milligram Daily Oral

Batch: **Started:** 05/04/1995 **Stopped:** 19/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				Increased clozapine plasma level.

Additional Information:

Report - 178679 is a sequence of 178680. the date of onset is not necessarily accurate but indicates onset sometime in the month. inability to maintain clozaril serum levels below 1000ug/l regardless of dose.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178680 **Seq:** 1 **Gender:** M
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:** 47
Onset Date: 28/02/2002 **DOB:** 05/01/1955
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Thinking abnormal			Treated with lipid lowering medication and insulin. patient hospitalised. clozaril therapy reduced to 100mg/bd and ceased on 19/08/02

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 05/04/1995 **Stopped:** 19/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Inability to maintain clozaril serum levels below 1000 ug/l regardless of dose

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. report - 178680 is a sequence of 178679.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178686 **Seq:** 1 **Gender:** M
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 08/11/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient is asymptomatic.	
Hypokinesia		Ventricular hypokinesia.	
Myocarditis			Patient was treated with ramipril.

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 02/07/1993 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				An echocardiogram showed moderate left ventricular enlargement, moderate to severe left ventricular dysfunction consistent with cardiomyopathy. myocarditis was diagnosed. echocardiogram showed ejection fraction 28%, non specific intraventricular delay.

Additional Information:

Cardiologist has been consulted. the patient denies symptoms of cardiac dysfunction 177943 is a duplicate of 178686.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178687 **Seq:** 1 **Gender:** M
Reported: 02/09/2002 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 15/08/2002 **DOB:** 29/07/1974
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Troponin increased			Clozaril discontinued.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/08/2002 **Stopped:** 15/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin		15/08/2002	0.52	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178711 **Seq:** 1 **Gender:** F
Reported: 04/09/2002 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 15/08/2002 **DOB:** 18/03/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder			Clopine therapy ceased. therapy dates 31/7/02 to 7/8/02 to 15/8/02.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet 13.0 Milligram Daily Oral
Batch: **Started:** 31/07/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178722 **Seq:** 1
Reported: 13/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 13/08/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 38
DOB: 12/11/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic steatosis			
Hypoglycaemia			
Influenza like illness	Caused or prolonged inpatient hospitalisation		Patient was hospitalised.
Lipase increased			
Pancreatitis	Caused or prolonged inpatient hospitalisation		Patient was hospitalised.
Somnolence			

Medicine Details:

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

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

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Other data				
17/12/2002	lipase	< 70 U/L	23/07/2003	5660	
17/12/2002	lipase	< 70 U/L	23/07/2003	4150	
17/12/2002	lipase	< 70 U/L	23/07/2003	801	
17/12/2002	lipase	< 70 U/L	23/07/2003	121	
17/12/2002	lipase	< 70 U/L	23/07/2003	94	
17/12/2002	lipase	< 70 U/L	23/07/2003	107	

Additional Information:

Hypoglycaemic medication unknown. reaction occurred 3.5 years after commencing clozaril. no alcohol consumption for the last 12 months and no evidence of gallstones. Mental disorder nos due to general medical condition. Measures taken to treat the events included a dose reduction of clozaril on 14/08/2002 to 100mg mane, 100mg midday, 200mg nocte. The dose was reduced to 300mg/day on 20/08/2002 and it was later further reduced to 200mg/d. Other factors could have contributed to the events, such as administration of oral hyperglycaemics. Clozaril was continued at a lower dose without any problems.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178722 **Seq:** 1
Reported: 13/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 13/08/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 38
DOB: 12/11/1963
Causality: Causality possible

Reaction Details:

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 400.0 Milligram Daily Oral
Batch: **Started:** 03/02/1999 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	lipase	< 70 U/L	23/07/2003	77	
17/12/2002	lipase	< 70 U/L	23/07/2003	79	

Additional Information:

Hypoglycaemic medication unknown. reaction occurred 3.5 years after commencing clozaril. no alcohol consumption for the last 12 months and no evidence of gallstones. Mental disorder nos due to general medical condition. Measures taken to treat the events included a dose reduction of clozaril on 14/08/2002 to 100mg mane, 100mg midday, 200mg nocte. The dose was reduced to 300mg/day on 20/08/2002 and it was later further reduced to 200mg/d. Other factors could have contributed to the events, such as administration of oral hyperglycaemics. Clozaril was continued at a lower dose without any problems.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178761 **Seq:** 1 **Gender:** M
Reported: 06/09/2002 **Weight:**
Hospitalisation: **Age:** 22
Onset Date: 12/08/2002 **DOB:** 08/08/1980
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis			Clozaril was ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 375.0 Milligram Daily Oral
Batch: **Started:** 03/05/2002 **Stopped:** 16/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		27/08/2002	0.30	
	White blood cells		27/08/2002	2.60	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178762 **Seq:** 1
Reported: 06/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 23/08/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 36
DOB: 15/03/1966
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ketosis Diabetes mellitus Hyperglycaemia Shock		Diabetic ketoacidosis.	Patient was admitted to intensive care unit and intubated.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 600.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms 9 years after commencing clozaril therapy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178773 **Seq:** 1
Reported: 06/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2002
Outcome: Recovered

Gender: M
Weight:
Age: 26
DOB: 11/04/1976
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion			Clozaril was ceased. patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia

Tablet 250.0 Milligram Daily Oral

Batch: **Started:** 12/06/2002 **Stopped:** 08/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178774 **Seq:** 1 **Gender:** M
Reported: 06/09/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: **DOB:** 23/12/1952
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly		Dilatation ventricular	Ceased clozaril

Medicine Details:

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 900.0 Milligram Daily Oral
Batch: **Started:** 18/04/2002 **Stopped:** 21/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178898 **Seq:** 1 **Gender:** F
Reported: 30/05/2002 **Weight:**
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Dyspnoea Electrocardiogram abnormal Pericarditis Pleuritic pain Tachycardia Troponin increased		Sharp like a knife.	Patient was treated with paracetamol 1gm orally.

Medicine Details:

BENZTROPINE MESYLATE (Other drug)			**Reason:**		
Oral application	2.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**		
Oral application	2.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
CLOZAPINE (Suspected)			**Reason:**		
Tablet	25.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				An ecg showed p-mitrale in lead i. t-wave flattening in lead iii. st-segment elevation concave upward across all leads, and a biphasic p-wave in v1.

Additional Information:

Australian and new zealand journal of psychiatry 2001. 36(1):143.4, 2002 feb. clozapine, 25mg daily, was commenced 3 weeks prior, and increased to 100mg daily over 2 weeks.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 178898 **Seq:** 1 **Gender:** F
Reported: 30/05/2002 **Weight:**
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

BENZTROPINE MESYLATE (Other drug)			**Reason:**		
Oral application	2.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**		
Oral application	2.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
CLOZAPINE (Suspected)			**Reason:**		
Tablet	25.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Troponin				Blood tests initially revealed a rise in serum troponin i of 1.89ug/l (normal, <0.4), decreasing the following day to 0.29 ug/l (normal,<0.4). two weeks later, her troponin i level was <0.04 ug/l (normal,<0.4), with complete symptom resolution. on commencement of clozapine, 3 weeks prior to admission, her troponin i was 0.34ug/l (normal,0.4).

Additional Information:

Australian and new zealand journal of psychiatry 2001. 36(1):143.4, 2002 feb. clozapine, 25mg daily, was commenced 3 weeks prior, and increased to 100mg daily over 2 weeks.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179018 **Seq:** 1 **Gender:** M
Reported: 13/09/2002 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 28/10/2001 **DOB:** 21/03/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			Treated with antidiabetic medication.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 375.0 Milligram Daily Oral

Batch: **Started:** 19/02/1999 **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. patients father is also diabetic.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179057 **Seq:** 1
Reported: 16/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/08/2002
Outcome: Recovered

Gender: M
Weight:
Age: 60
DOB: 11/03/1942
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal Pyrexia			Patient was hospitalised. clozaril ceased.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 175.0 Milligram Daily Oral

Batch: **Started:** 01/08/2002 **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.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179058 **Seq:** 1 **Gender:** M
Reported: 16/09/2002 **Weight:** 0.00
Hospitalisation: **Age:** 36
Onset Date: 12/08/2002 **DOB:** 06/02/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerks.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 01/08/2002 **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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179059 **Seq:** 1 **Gender:** M
Reported: 16/09/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 28/08/2002 **DOB:** 26/06/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Anaemia Eosinophilia Myocarditis Tachycardia		St segment depression	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	250.0 Milligram	Daily	Oral	
Batch:	**Started:** 16/07/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Patient's routine ecg showed an anteroseptal myocardial infarct (possibly old) and minor interoseptal st changes on 28.8.02, approximatley 6 weeks after commencing clozaril. (date unknown) pulse 90 beats per minute (bpm).
	Eosinophils	0.04 TO 0.40	27/08/2002	0.42	
	Haemoglobin	135 - 180	27/08/2002	130	
	Neutrophils		16/07/2002	2.10	

Additional Information:

No past cardiac history and also no baseline ecg. p/h of alcoholism. family history - myocardial ischaemia and the patient's father died at a young age of heart disease. risk factors of ischaemic heart disease (ihd): family history of ihd, increased blood sugar levels (bsl); increased alcohol intake and increased triglycerides (tg). report 179538 is a duplicate of this report.

Report Details:

Case Number: 179059 **Seq:** 1 **Gender:** M
Reported: 16/09/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 28/08/2002 **DOB:** 26/06/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)			**Reason:** Unspecified schizophrenia	
Tablet	250.0 Milligram	Daily	Oral	
Batch:	**Started:** 16/07/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		28/08/2002	2.00	
	Neutrophils		27/08/2002	2.0	
	Other data				10.9.02 - normal left ventricular size anbd systolic function, ejection fraction of 60% and normal valves. the holter monitor report showed that the atient had sinus rhythm (with a mean heart rate of 108 beats/min), infrequent, uniform and isolated ventricular actopy and the patient had a symptomatic recording period.

Additional Information:

No past cardiac history and also no baseline ecg. p/h of alcoholism. family history - myocardial ischaemia and the patient's father died at a young age of heart disease. risk factors of ischaemic heart disease (ihd): family history of ihd, increased blood sugar levels (bsl); increased alcohol intake and increased triglycerides (tg). report 179538 is a duplicate of this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179059 **Seq:** 1 **Gender:** M
Reported: 16/09/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 28/08/2002 **DOB:** 26/06/1981
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	250.0 Milligram	Daily	Oral	
Batch:	**Started:** 16/07/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		04/10/2002	480	Clozaril level.
	White blood cells		16/07/2002	5.30	
	White blood cells		27/08/2002	5.20	
	White blood cells		28/08/2002	5.20	

Additional Information:

No past cardiac history and also no baseline ecg. p/h of alcoholism. family history - myocardial ischaemia and the patient's father died at a young age of heart disease. risk factors of ischaemic heart disease (ihd): family history of ihd, increased blood sugar levels (bsl); increased alcohol intake and increased triglycerides (tg). report 179538 is a duplicate of this report.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179060 **Seq:** 1 **Gender:** M
Reported: 16/09/2002 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 10/08/2002 **DOB:** 21/01/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia Anaemia Atrial fibrillation Diarrhoea Hepatic function abnormal Influenza like illness Malaise Tachycardia Vomiting		Persistent eosinophilla.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 01/08/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Eosinophils				Persistent eosinophilla of 1.06.

Additional Information:

Relevant history - alcohol abuse.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179061 **Seq:** 1 **Gender:** F
Reported: 16/09/2002 **Weight:**
Hospitalisation: **Age:** 19
Onset Date: 28/08/2002 **DOB:** 30/12/1982
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Anorexia Diarrhoea Fatigue Hallucination Headache Influenza like illness Nausea			Clozaril dose reduced.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 225.0 Milligram Daily Oral

Batch: **Started:** 01/08/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179110 **Seq:** 1 **Gender:** M
Reported: 18/09/2002 **Weight:**
Hospitalisation: Hospitalisation prolonged **Age:** 24Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia Apathy			Patient was transferred to a mental hospital.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This report - 179110 is a sequence to 179108 and 179109. description to amnesia - signs of memory loss, childishness, withdrawn nature and fails to care for himself.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179114 **Seq:** 1 **Gender:** M
Reported: 18/09/2002 **Weight:**
Hospitalisation: **Age:** 27
Onset Date: 28/08/2002 **DOB:** 21/04/1975
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomegaly		Patient was asymptomatic.	Non-drug treatment patient monitored.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)			**Reason:**		
Oral application	0.0			Oral	
Batch:	**Started:** 01/08/1997			**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia	
Tablet	600.0	Milligram	Daily	Oral	
Batch:	**Started:** 01/01/1997			**Stopped:**	CONTIN
TEGRETOL (Suspected)			**Reason:**	Other&unspecified epilepsy	
Oral application	400.0	Milligram	Daily	Oral	
Batch:	**Started:** 01/01/1998			**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Enlarged ventricle: reduced ejection fraction of 68% (ejection fraction decreased. echocardiogram showed a slightly enlarged ventricle with reduced ejection fraction of 68% (>60).

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the year. the dose start date for clozaril and tegretol is not necessarily accurate but indicates drugs were started sometime in the year. the patient had received clozaril and tegretol before and did not develop similar or other symptoms.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179195 **Seq:** 1 **Gender:** M
Reported: 23/09/2002 **Weight:**
Hospitalisation: **Age:** 20
Onset Date: 08/09/2002 **DOB:** 09/01/1982
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension Urinary incontinence			Treatment - splitting the patient's clozaril dose into smaller doses.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 600.0 Milligram Daily Oral

Batch: **Started:** 05/08/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Relevant history - polydipsia and hepatitis c.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179241 **Seq:** 1 **Gender:** M
Reported: 30/09/2002 **Weight:**
Hospitalisation: **Age:** 15Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain from 60 to 100kg.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 0.0 Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179340 **Seq:** 1
Reported: 23/09/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 52
DOB: 14/10/1949
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			
Respiratory distress	Caused or prolonged inpatient hospitalisation		Admitted to hospital.
Tachycardia			
Thrombocytopenia	Caused or prolonged inpatient hospitalisation		Admitted to hospital.

Medicine Details:

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

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

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 13/05/2002 **Stopped:** 16/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2002	Platelets		05/12/2002	90	

Additional Information:

Relevent history - heart rate increase. the patient's pulse rate was high before clozaril dose was increased from 400mg to 500mg/daily. patient was a heavy smoker. ceased clozaril on 15/10/02 due to lack of efficacy and a terminal illness diagnosed.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179352 **Seq:** 1 **Gender:** F
Reported: 23/09/2002 **Weight:**
Hospitalisation: **Age:** 21
Onset Date: 06/09/2002 **DOB:** 18/09/1980
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Shock			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 12.5 Milligram Daily Oral

Batch: **Started:** 19/08/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179487 **Seq:** 1
Reported: 30/09/2002
Hospitalisation: Admitted to hospital
Onset Date: 22/07/2002
Outcome: Recovered

Gender: F
Weight:
Age: 66
DOB: 30/05/1936
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Angina pectoris Myocardial infarction		Acute myocardial infarction.	Patient was hospitalised. treated with glyceryl trinitrate spray, unspecified beta blocker.

Medicine Details:

RANITIDINE (Other drug) **Reason:** Othr&unspec metabolic diseases

0.0

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

CLOZARIL (Suspected) **Reason:**

Tablet 275.0 Milligram Daily Oral

Batch: **Started:** 27/01/1998 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

High cholesterol and a family history of one first degree relative deceased due to a heart attack at age 67; the patient never smoked and did not suffer from hypertension.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179493 **Seq:** 1 **Gender:** U
Reported: 30/09/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179537 **Seq:** 1
Reported: 02/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/09/2002
Outcome: Unknown

Gender: M
Weight:
Age: 27
DOB: 10/10/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia Pyrexia		Severe pneumonia complicated by septic shock.	Clozaril treatment was interrupted for 3 to 4 days. patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 13/04/1994 **Stopped:** 14/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179539 **Seq:** 1 **Gender:** M
Reported: 02/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 11/09/2002 **DOB:** 07/09/1972
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation			
Blood creatine phosphokinase incr			
Chills			
Hyperhidrosis			
Leukocytosis			
Malaise			
Pyrexia			
Tachycardia			
Troponin increased			
Hypertension		BP 160/100	
Chest pain		Central chest pain	

Medicine Details:

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

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

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

CLOZARIL (Suspected) **Reason:**
Tablet 175.0 Milligram Daily Oral
Batch: **Started:** 30/08/2002 **Stopped:** 13/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/10/2002	Chest X-ray				12/09/2002 - Chest x-ray. There are no previous chest x-ray for comparison. The heart is not enlarged and the cardiomediastinal contour is normal. The lungs and pleural spaces are clear with no evidence of collapse or consolidation.
16/12/2002	Creatine		13/09/2002	344	
16/12/2002	Creatine		13/09/2002	274	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179539 **Seq:** 1 **Gender:** M
Reported: 02/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 11/09/2002 **DOB:** 07/09/1972
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Three days of intermittent fever with chills and night sweats and malaise and isolated episode of brief central chest pain which resolved spontaneously.	Clozaril ceased.

Medicine Details:

HYDROCORTISONE (Other drug)			**Reason:**	
Ointment	0.0			Topical
Batch:	**Started:**		**Stopped:**	
ELOCON (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
Tablet	175.0	Milligram	Daily	Oral
Batch:	**Started:**	30/08/2002	**Stopped:**	13/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2002	Creatine phosphokinase		15/09/2002	100	
16/12/2002	Creatine phosphokinase		14/09/2002	243	
16/12/2002	Creatine phosphokinase		16/09/2002	48	
16/12/2002	Creatine phosphokinase		18/09/2002	86	
02/10/2002	Echocardiogram				Transthoracic ECHO - normal study 28/03/2003
02/10/2002	Electrocardiograph				13 September 2002: non-especific ECG changes
02/10/2002	Haemoglobin		13/09/2002	170	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179539 **Seq:** 1 **Gender:** M
Reported: 02/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 11/09/2002 **DOB:** 07/09/1972
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

HYDROCORTISONE (Other drug)			**Reason:**	
Ointment	0.0			Topical
Batch:	**Started:**		**Stopped:**	
ELOCON (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
Tablet	175.0 Milligram	Daily		Oral
Batch:	**Started:** 30/08/2002		**Stopped:**	13/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/10/2002	Platelets		13/09/2002	250	
16/12/2002	Troponin		13/09/2002	41.6	
16/12/2002	Troponin		09/09/2002	0.5	
16/12/2002	Troponin		11/09/2002	0.7	
16/12/2002	Troponin		12/09/2002	0.4	
16/12/2002	Troponin		07/08/2003	41.6	
16/12/2002	Troponin		13/09/2002	34.7	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179539 **Seq:** 1 **Gender:** M
Reported: 02/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 30
Onset Date: 11/09/2002 **DOB:** 07/09/1972
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

HYDROCORTISONE (Other drug)			**Reason:**	
Ointment	0.0			Topical
Batch:	**Started:**		**Stopped:**	
ELOCON (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
DIAZEPAM (Other drug)			**Reason:**	
	0.0			
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	
Tablet	175.0 Milligram	Daily		Oral
Batch:	**Started:** 30/08/2002		**Stopped:**	13/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2002	Troponin		13/09/2002	19.7	
16/12/2002	Troponin		14/09/2002	22.1	
16/12/2002	Troponin		15/09/2002	6.0	
16/12/2002	Troponin		16/09/2002	1.7	
16/12/2002	Troponin		18/09/2002	0.6	
02/10/2002	White blood cells		13/09/2002	13.2	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179652 **Seq:** 1
Reported: 08/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 03/09/2002
Outcome: Recovered

Gender: M
Weight:
Age: 41
DOB: 21/01/1961
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gastroenteritis Influenza like illness	Severe		Patient required antibiotics. clozaril was discontinued. patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 22/07/2002 **Stopped:** 10/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179751 **Seq:** 1 **Gender:** F
Reported: 08/10/2002 **Weight:**
Hospitalisation: **Age:** 41
Onset Date: 01/01/2002 **DOB:** 17/06/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cataract		Cataracts in both eyes.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	1.0 Gram	Daily	Oral
Batch:	**Started:** 03/11/1993	**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179753 **Seq:** 1 **Gender:** M
Reported: 08/10/2002 **Weight:**
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 23/08/1969
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal			

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 600.0 Milligram Daily Oral
Batch: **Started:** 20/04/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrocardiograph				Echo cardiograph reported abnormal septal motion and mild global hypokinesis.

Additional Information:

The echo changes could be related to myocardial impairment/cardiomyopathy secondary to clopine. patient history of chronic paranoid schizophrenia.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179766 **Seq:** 1 **Gender:** M
Reported: 08/10/2002 **Weight:**
Hospitalisation: **Age:** 37
Onset Date: 01/01/2002 **DOB:** 17/12/1964
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			Treated with oral hyperglycaemic agents (not specified).

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 06/09/1996 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179842 **Seq:** 1
Reported: 14/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 18/09/2002
Outcome: Recovered

Gender: M
Weight:
Age: 24
DOB: 10/05/1978
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Electrocardiogram abnormal Electroencephalogram abnormal Hypertension			Clozaril dose reduced to 500mg daily and patient recovered. patient was hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 700.0 Milligram Daily Oral

Batch: **Started:** 20/11/2001 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179887 **Seq:** 1
Reported: 18/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 26/09/2002
Outcome: Unknown

Gender: F
Weight:
Age: 31
DOB: 02/02/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension Nausea Vomiting			Patient hospitalised. given antiemetics.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 27/05/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179940 **Seq:** 1
Reported: 18/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 15/09/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 28
DOB: 28/01/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 450.0 Milligram Daily Oral

Batch: **Started:** 13/09/2002 **Stopped:** 19/09/2002

QUETIAPINE (Suspected) **Reason:**

Tablet 1.1 Gram Daily Oral

Batch: **Started:** 07/07/2002 **Stopped:** 17/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/10/2002	Creatine phosphokinase		20/09/2002	2356	
18/10/2002	Creatine phosphokinase		21/09/2002	2073	
18/10/2002	Creatine phosphokinase		22/09/2002	991	
18/10/2002	Creatine phosphokinase		24/09/2002	248	

Additional Information:

Concomitant quetiapine was weaned off at the time of the event

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179942 **Seq:** 1 **Gender:** F
Reported: 18/10/2002 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: **DOB:** 14/07/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis			Clozaril discontinued.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179947 **Seq:** 1 **Gender:** M
Reported: 18/10/2002 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: 02/10/2002 **DOB:** 27/05/1967
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia			Atenolol

Medicine Details:

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

CLOZARIL (Suspected) **Reason:** Schizophrenia
Tablet 300.0 Milligram Daily Oral
Batch: **Started:** 26/08/2002 **Stopped:** 09/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Not yet recovered but recovering. Report 192906 is a seq 2.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179948 **Seq:** 1
Reported: 18/10/2002
Hospitalisation:
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 48
DOB: 23/07/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension Tachycardia			Trandolapril

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 200.0 Milligram Daily Oral

Batch: **Started:** 19/09/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Hypertension may have been a pre-existing condition.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179949 **Seq:** 1 **Gender:** F
Reported: 18/10/2002 **Weight:**
Hospitalisation: **Age:** 49
Onset Date: 02/10/2002 **DOB:** 27/12/1952
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Clozaril briefly discontinued to treat the reaction. patient had stopped taking clozaril therapy herself.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 25.0 Milligram Daily Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Current condition: liver function tests nos abnormal, history of poor liver function.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179950 **Seq:** 1
Reported: 18/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/09/2002
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 52
DOB: 09/02/1950
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion Drug level increased			

Medicine Details:

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

CLOZARIL (Interaction) **Reason:** Unspecified schizophrenia
Tablet 800.0 Milligram Daily Oral
Batch: **Started:** 26/08/2002 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2002	Serum drug level	(150-500)	08/08/2003	2300	
16/12/2002	Serum drug level	(150-500)	30/09/2002	2310	
16/12/2002	Serum drug level	(150-500)	07/10/2002	470	
16/12/2002	Serum drug level		30/09/2002	1300 UG/L	
16/12/2002	Serum drug level		07/10/2002	490 UG/L	

Additional Information:

Clozaril dossage was decreased to 400mg/day and efexor treatment was ceased.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179951 **Seq:** 1
Reported: 18/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 23/09/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 39
DOB: 16/03/1963
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction Colitis Crohn's disease		Small intestinal obstruction.	Patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 125.0 Milligram Daily Oral

Batch: **Started:** 12/09/2002 **Stopped:** 27/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Description: suspected colitis, small bowel obstruction or exacerbation of crohn's disease approximately 2 weeks after commencing clozaril therapy. historical condition: gastrointestinal disorder nos and pre-existing gast- rointestinal condition.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179952 **Seq:** 1
Reported: 18/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 17/09/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 47
DOB: 02/10/1954
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Hyperhidrosis Lethargy Pneumonia Tachycardia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	300.0 Milligram	Daily	Oral
Batch:	**Started:** 23/07/2002	**Stopped:**	24/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/10/2002	Echocardiogram				

Additional Information:

Patient also taking benztropine, omeprazole, multivitamins (panthenol, retinol). All of the symptoms had completely resolved by 28 September 2002.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179977 **Seq:** 1 **Gender:** M
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 19
Onset Date: 28/09/2002 **DOB:** 28/08/1983
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Choking Dysphagia Salivary hypersecretion Tachycardia			Benztropine.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 01/09/2002 **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 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179981 **Seq:** 1 **Gender:** F
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 21/08/2001 **DOB:** 06/12/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			Clozapine ceased.

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet 37.0 Milligram Daily Oral
Batch: **Started:** 05/04/2001 **Stopped:** 23/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		05/04/2001	1.9	
	Neutrophils		12/04/2001	2.2	
	Neutrophils		23/05/2001	2.7	
	Neutrophils		02/08/2001	5.2	
	Neutrophils		18/08/2001	2.7	
	Neutrophils		16/08/2001	1.5	
	Neutrophils		15/08/2001	5.4	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179981 **Seq:** 1 **Gender:** F
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 21/08/2001 **DOB:** 06/12/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected)			**Reason:**	
Tablet	37.0 Milligram		Daily	Oral
Batch:	**Started:** 05/04/2001		**Stopped:**	23/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		27/06/2001	2.6	
	Neutrophils		20/08/2001	2.3	
	Neutrophils		19/09/2001	2.7	
	Neutrophils		27/08/2001	3.3	
	Neutrophils		24/08/2001	2.5	
	Neutrophils		23/08/2001	1.6	
	Neutrophils		22/08/2001	1.3	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179981 **Seq:** 1 **Gender:** F
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 21/08/2001 **DOB:** 06/12/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected) **Reason:**

Tablet 37.0 Milligram Daily Oral

Batch: **Started:** 05/04/2001 **Stopped:** 23/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		21/08/2001	1.3	
	White blood cells		05/04/2001	3.9	
	White blood cells		12/04/2001	4.4	
	White blood cells		23/05/2001	4.7	
	White blood cells		27/06/2001	4.6	
	White blood cells		02/08/2001	7.0	
	White blood cells		15/08/2001	5.4	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179981 **Seq:** 1 **Gender:** F
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 21/08/2001 **DOB:** 06/12/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected) **Reason:**

Tablet	37.0 Milligram	Daily	Oral
Batch:	**Started:** 05/04/2001	**Stopped:**	23/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		16/08/2001	3.9	
	White blood cells		18/08/2001	4.1	
	White blood cells		20/08/2001	4.2	
	White blood cells		21/08/2001	3.2	
	White blood cells		22/08/2001	3.7	
	White blood cells		23/08/2001	3.5	
	White blood cells		24/08/2001	4.2	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179981 **Seq:** 1 **Gender:** F
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 50
Onset Date: 21/08/2001 **DOB:** 06/12/1950
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Medicine Details:

CLOZAPINE (Suspected) **Reason:**

Tablet 37.0 Milligram Daily Oral

Batch: **Started:** 05/04/2001 **Stopped:** 23/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	White blood cells		27/08/2001	4.9	
	White blood cells		19/09/2001	4.3	

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 179987 **Seq:** 1 **Gender:** M
Reported: 21/10/2002 **Weight:**
Hospitalisation: **Age:** 28
Onset Date: 17/09/2002 **DOB:** 28/01/1974
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr Neuroleptic malignant syndrome Pyrexia Tachycardia			Clozapine and quetiapine ceased.

Medicine Details:

DIAZEPAM (Other drug) **Reason:**
15.0 Milligram Daily
Batch: **Started:** 06/09/2002 **Stopped:** 17/09/2002

KENACOMB OTIC (Other drug) **Reason:**
Ear Drops 6.0 Dose Unspecified Daily Topical
Batch: **Started:** **Stopped:** CONTIN

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 5.0 Milligram Daily Oral
Batch: **Started:** 16/09/2002 **Stopped:** 18/09/2002

QUETIAPINE (Suspected) **Reason:**
Tablet 1.1 Gram Daily Oral
Batch: **Started:** 07/07/2002 **Stopped:** 17/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine phosphokinase		19/09/2002	3675	(ck - 3000).
	Creatine phosphokinase		21/09/2002	203	(ck - 3000).
	Creatine phosphokinase		24/09/2002	248	(ck - 3000).

Additional Information:

Previouse exposure to drug.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180041 **Seq:** 1 **Gender:** M
Reported: 24/10/2002 **Weight:**
Hospitalisation: **Age:** 24
Onset Date: 14/10/2002 **DOB:** 11/04/1978
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

CLOZAPINE (Suspected) **Reason:**
Tablet 500.0 Milligram Daily Oral
Batch: **Started:** 06/09/2000 **Stopped:** 14/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Neutrophils		14/10/2002	1.2	
	Neutrophils		17/10/2002	2.2	
	White blood cells		14/10/2002	4.3	

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180126 **Seq:** 1
Reported: 28/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 13/10/2002
Outcome: Unknown

Gender: F
Weight:
Age: 28
DOB: 19/09/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Suicide attempt			Patient was hospitalised for 9 days and clopine was re-introduced on 21/10/02 at a dose level of 25mg.

Medicine Details:

CLOPINE (Suspected) **Reason:**

Tablet 400.0 Milligram Daily Oral

Batch: **Started:** 08/10/2002 **Stopped:** 13/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180132 **Seq:** 1
Reported: 23/10/2002
Hospitalisation: Admitted to hospital
Onset Date: 01/10/2002
Outcome: Unknown

Gender: M
Weight:
Age: 27
DOB: 07/10/1974
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Dyspnoea Pericardial effusion Pneumonia			Patient was admitted to hospitalised.

Medicine Details:

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

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

LITHIUM CARBONATE (Other drug) **Reason:**
0.0
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:**
Tablet 700.0 Milligram Daily Oral
Batch: **Started:** 13/08/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180134 **Seq:** 1 **Gender:** U
Reported: 23/10/2002 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased Malaise Tachycardia			Treated with atenolol.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	400.0	Milligram	Daily	Oral

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Clozaril plasma level of 810ng/ml in oct 2002.

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180260 **Seq:** 1 **Gender:** M
Reported: 31/10/2002 **Weight:**
Hospitalisation: **Age:** 31
Onset Date: 28/10/2002 **DOB:** 29/09/1971
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome			Ceased clopine.

Medicine Details:

CLOPINE (Suspected) **Reason:**
Tablet 25.0 Milligram Daily Oral
Batch: **Started:** 22/10/2002 **Stopped:** 24/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180427 **Seq:** 1 **Gender:** M
Reported: 11/11/2002 **Weight:**
Hospitalisation: **Age:** 32
Onset Date: 28/06/2001 **DOB:** 02/06/1969
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia			Given insulin.

Medicine Details:

COGENTIN (Other drug) **Reason:**
Oral application 2.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

SERTRALINE HYDROCHLORIDE (Other drug) **Reason:**
100.0 Milligram Daily
Batch: **Started:** **Stopped:**

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 200.0 Milligram Daily Oral
Batch: **Started:** 20/03/2000 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		13/06/2001	0.9	
	Serum drug level		18/06/2001	1.4	
	Serum drug level		26/06/2001	1.2	
	Serum glucose		13/06/2001	19.7	Blood sugar level (>20 - units unspecified.

Additional Information:

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

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180447 **Seq:** 1 **Gender:** M
Reported: 08/11/2002 **Weight:**
Hospitalisation: **Age:** 29
Onset Date: 23/10/2002 **DOB:** 26/07/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericarditis			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 23/08/2002 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Cardiologist diagnosed pericarditis.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180448 **Seq:** 1 **Gender:** F
Reported: 08/11/2002 **Weight:**
Hospitalisation: **Age:** 60
Onset Date: 21/10/2002 **DOB:** 09/04/1942
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia			Treated with iv and oral antibiotics.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 525.0 Milligram Daily Oral

Batch: **Started:** 23/02/1999 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The reporter casulity was stated as not related.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180450 **Seq:** 1
Reported: 08/11/2002
Hospitalisation: Admitted to hospital
Onset Date: 06/08/2002
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 47
DOB: 02/10/1954
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Left ventricular failure			

Medicine Details:

OMEPRAZOLE (Other drug)			**Reason:**	
Oral application	0.0			Oral
Batch:	**Started:**		**Stopped:**	
BENZTROPINE MESYLATE (Other drug)			**Reason:**	
Oral application	0.0			Oral
Batch:	**Started:**		**Stopped:**	
CLOZARIL (Suspected)			**Reason:**	Unspecified schizophrenia
Tablet	300.0 Milligram	Daily		Oral
Batch:	**Started:** 30/07/2002		**Stopped:**	01/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2002	Electrographics				Echo indicated reduced left ventricular function.

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180468 **Seq:** 1
Reported: 11/11/2002
Hospitalisation: Admitted to hospital
Onset Date: 25/10/2002
Outcome: Not yet recovered

Gender: M
Weight:
Age: 32
DOB: 28/10/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukopenia Neutropenia Pneumonia			Patient hospitalised.

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 16/07/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Description: suppressed neutropil count (neutropil count increased) suppressed white blood cell count (white blood cell count decreased). medical hitory - diabetes mellitus nos.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180471 **Seq:** 1
Reported: 11/11/2002
Hospitalisation: Admitted to hospital
Onset Date: 16/09/2002
Outcome: Recovered

Gender: M
Weight: 65.00
Age: 45
DOB: 19/10/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia			Clozaril ceased. given gcsf injections. hospitalised. date of recovery 09/10/02.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Capsule 250.0 Milligram Daily Oral
Batch: **Started:** 01/03/1997 **Stopped:** 19/09/2002

FLUDARABINE PHOSPHATE (Suspected) **Reason:** Otr prim malig n lymphoid tisu
Injection 50.0 Milligram Daily Intravenous
Batch: **Started:** 21/08/2002 **Stopped:** 23/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had previously had 2 cycles of "chop" chemotherapy and 2 cycles of "ice" salvage regimen with no serious myelosupression. the dose start date for the drug clozapine is not necessarily accurate but indicates the drug was started sometime in the month.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180475 **Seq:** 1
Reported: 11/11/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 48
DOB: 14/12/1953
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation		Patient admitted to hospital. treated with iv ceftriaxone 1g/d and hydrocortisone 100mg IV qid.

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:** contin

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** 25/10/2002 **Stopped:** 28/10/2002

CLOZARIL (Suspected) **Reason:**
Tablet 650.0 Milligram Daily Oral
Batch: **Started:** 16/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Neutrophils		22/07/2003	8.69	
17/12/2002	Neutrophils		22/07/2003	8.79	
17/12/2002	Neutrophils		22/07/2003	9.40	
17/12/2002	Neutrophils		22/07/2003	8.00	
17/12/2002	Neutrophils		22/07/2003	4.00	
17/12/2002	Neutrophils		22/07/2003	8.50	
17/12/2002	White blood cells		22/07/2003	10.8	

Additional Information:

Past medical history - patient was a heavy smoker and the patient's pulse rate was high before the recent dosage increase in clozaril from 400-500mg/daily. Previous alcohol abuse.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180475 **Seq:** 1
Reported: 11/11/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 48
DOB: 14/12/1953
Causality: Causality possible

Reaction Details:

Medicine Details:

SODIUM VALPROATE (Other drug) **Reason:**
Batch: **Started:** **Stopped:** contin

DIAZEPAM (Other drug) **Reason:**
Batch: **Started:** 25/10/2002 **Stopped:** 28/10/2002

CLOZARIL (Suspected) **Reason:**
Tablet 650.0 Milligram Daily Oral
Batch: **Started:** 16/05/2001 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	White blood cells		22/07/2003	11.10	
17/12/2002	White blood cells		22/07/2003	11.50	
17/12/2002	White blood cells		22/07/2003	10.80	
17/12/2002	White blood cells		22/07/2003	5.330	
17/12/2002	White blood cells		22/07/2003	10.30	

Additional Information:

Past medical history - patient was a heavy smoker and the patient's pulse rate was high before the recent dosage increase in clozaril from 400-500mg/daily. Previous alcohol abuse.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180476 **Seq:** 1
Reported: 11/11/2002
Hospitalisation: Admitted to hospital
Onset Date: 24/10/2002
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 53
DOB: 22/01/1949
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia			

Medicine Details:

CLOZARIL (Suspected) **Reason:**

Tablet 25.0 Milligram Daily Oral

Batch: **Started:** 10/02/2002 **Stopped:** 25/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180485 **Seq:** 1 **Gender:** M
Reported: 11/11/2002 **Weight:** 0.00
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 19/10/1956
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 275.0 Milligram Daily Oral
Batch: **Started:** 20/02/1997 **Stopped:** 22/08/2002

FLUDARABINE PHOSPHATE (Suspected) **Reason:** Otr prim malig n lymphoid tisu
2.0 Dose Unspecified Cyclical
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Current medical condition - non-Hodgkin's lymphoma. As treatment for this, patient had previously had two cycles of CHOP chemotherapy and two cycles of ICE salvage chemotherapy. No such problems were encountered with previous chemotherapy.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180632 **Seq:** 1 **Gender:** F
Reported: 14/11/2002 **Weight:**
Hospitalisation: **Age:** 40
Onset Date: 31/12/1994 **DOB:** 15/10/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neurosis			Commenced serteraline. required a visit to doctor.

Medicine Details:

CLOPINE (Suspected) **Reason:** Unspecified schizophrenia

Tablet 350.0 Milligram Daily Oral

Batch: **Started:** 01/01/1994 **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The onset date is not necessariily accurate but indicates onset sometime in the year. the dose start date is not necessarily accurate but indicates clopine was started sometime in the year.

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180687 **Seq:** 1
Reported: 15/11/2002
Hospitalisation: Admitted to hospital
Onset Date: 16/09/2002
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 22
DOB: 17/07/1980
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthenia			
Body temperature increased			
Dizziness			
Hypotension			
Influenza like illness			
Lethargy			
Malaise			
Myalgia			
Myocarditis			
Troponin increased			

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
200.0 Milligram Daily Oral
Batch: **Started:** 04/09/2002 **Stopped:** 24/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180690 **Seq:** 1 **Gender:** F
Reported: 15/11/2002 **Weight:**
Hospitalisation: **Age:** 60
Onset Date: 28/10/2002 **DOB:** 03/05/1942
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis		Deep vein thrombosis	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	200.0 Milligram	Daily	Oral	
Batch:	**Started:** 14/06/2002		**Stopped:**	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of hypotension and diabetes before starting with clozaril.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180812 **Seq:** 1
Reported: 18/12/2002
Hospitalisation: Admitted to hospital
Onset Date: 28/10/2002
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 50
DOB: 11/09/1952
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Acute myocardial infarction		Acute myocardial infarction.	
Cardiac failure congestive		Cardiac failure congestive.	
Hypertrophic cardiomyopathy		Hypertrophic cardiomyopathy.	
Mitral valve incompetence		Mitral valve incompetence.	
Ventricular hypokinesia		Ventricular hypokinesia.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 700.0 Milligram Daily Oral

Batch: **Started:** 26/06/1993 L TERM **Stopped:** 28/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Neutrophils				
18/12/2002	Other data				
17/12/2002	White blood cells				
17/12/2002	White blood cells				

Additional Information:

History: Past medical history of obstructive cardiomyopathy.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180874 **Seq:** 1
Reported: 19/12/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/11/2002
Outcome: Recovered

Gender: M
Weight: 64.00
Age: 41
DOB: 21/01/1961
Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinophilia Hepatic function abnormal Tachycardia		Eosinophilia, tachycardia, hepatic enzymosis	Ceased Clozapine, rehydration, changed to olanzapine, patient was hospitalised

Medicine Details:

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

Tablet 30.0 Milligram Daily Oral

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

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia

Tablet 75.0 Milligram Daily Oral

Batch: **Started:** 31/10/2002 **Stopped:** 13/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/12/2002	Bilirubin	(>17)	14/11/2002	566	
19/12/2002	Bilirubin	(>17)	20/11/2002	386	
19/12/2002	Bilirubin	(>17)	14/11/2002	552	
19/12/2002	Bilirubin	(>17)	20/11/2002	361	
19/12/2002	Bilirubin	(>17)	14/11/2002	210	
19/12/2002	Bilirubin	(>17)	20/11/2002	71	
19/12/2002	Bilirubin	(>17)	14/11/2002	79	

Additional Information:

Reaction occurred on rechallenge and improved on cessation of clozapine

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180874 **Seq:** 1
Reported: 19/12/2002
Hospitalisation: Admitted to hospital
Onset Date: 14/11/2002
Outcome: Recovered

Gender: M
Weight: 64.00
Age: 41
DOB: 21/01/1961
Causality: Causality certain

Reaction Details:

Medicine Details:

OXAZEPAM (Other drug)			**Reason:**	Specific disorders of sleep	
Tablet	30.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	CONTIN
CLOZAPINE (Suspected)			**Reason:**	Unspecified schizophrenia	
Tablet	75.0	Milligram	Daily	Oral	
Batch:	**Started:**	31/10/2002		**Stopped:**	13/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/12/2002	Bilirubin	(>17)	20/11/2002	23	
19/12/2002	Bilirubin	(>17)	14/11/2002	22	

Additional Information:

Reaction occurred on rechallenge and improved on cessation of clozapine

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180881 **Seq:** 1 **Gender:** M
Reported: 19/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 31Y
Onset Date: 29/10/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Prothrombin time prolonged		Lupus coagulant discovered on screening	Observation and follow-up

Medicine Details:

CLOZAPINE (Suspected) **Reason:** Unspecified schizophrenia
Tablet 750.0 Milligram Daily Oral
Batch: **Started:** L TERM **Stopped:**

ASPIRIN (Suspected) **Reason:** Chron isch heart dis no hyper
150.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

COLOXYL WITH SENNA (Suspected) **Reason:** Chron isch heart dis no hyper
Tablet Daily Oral
Batch: **Started:** **Stopped:**

ATORVASTATIN (Suspected) **Reason:** Othr&unspec metabolic diseases
Tablet 20.0 Milligram Daily Oral
Batch: **Started:** **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/12/2002	Activated partial thromboplastin	(25-38)			
19/12/2002	Immunology				

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180881 **Seq:** 1 **Gender:** M
Reported: 19/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 31Y
Onset Date: 29/10/2002 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Medicine Details:

RAMIPRIL (Suspected)			**Reason:**	Essential benign hypertension	
Capsule	2.5	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
LANSOPRAZOLE (Suspected)			**Reason:**		
Capsule	30.0	Milligram	Daily	Oral	
Batch:	**Started:**			**Stopped:**	
GLYCERYL TRINITRATE (Suspected)			**Reason:**	Chron isch heart dis no hyper	
Tablet			Daily	Oral	
Batch:	**Started:**			**Stopped:**	

Laboratory Investigations:

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180910 **Seq:** 1
Reported: 20/12/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 46
DOB: 19/10/1956
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancytopenia		Pancytopenia.	Treated with G-CSF.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet 274.0 Milligram Daily Oral
Batch: **Started:** 20/02/1997 L TERM **Stopped:** 22/08/2002

FLUDARABINE PHOSPHATE (Suspected) **Reason:** Hodgkin's disease
Injection 50.0 Milligram Daily Intravenous
Batch: **Started:** 21/08/2002 **Stopped:** 23/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

In January 2002, patient was diagnosed with a brain tumor. The patient was treated with chemotherapy and radiation therapy. Date of onset January 2002. 182198 is a duplicate

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180911 **Seq:** 1
Reported: 20/12/2002
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: U
Weight: 0.00
Age: 99U
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced a seizure after commencing Clozaril.	Treated with Sodium Valproate.

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia
Tablet Oral
Batch: **Started:** **Stopped:** CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 180913 **Seq:** 1
Reported: 20/12/2002
Hospitalisation: Admitted to hospital
Onset Date: 10/11/2002
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 47
DOB: 21/07/1955
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain Leukopenia Neutropenia Tachycardia		Patient experienced a decrease in white blood cell count and neutrophil count.	

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)				**Reason:** Depression		
Oral application	450.0	Milligram	Daily		Oral	
Batch:	**Started:** 27/03/2000			**Stopped:**		CONTIN
CLOPINE (Suspected)				**Reason:**		
Tablet	450.0	Milligram	Daily		Oral	
Batch:	**Started:**		L TERM	**Stopped:**	11/11/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/12/2002	Neutrophils		14/10/2002	2.6	
20/12/2002	Neutrophils		11/11/2002	1.1	
20/12/2002	White blood cells		14/10/2002	4.8	
20/12/2002	White blood cells		11/11/2002	2.9	

Additional Information:

Patient's history - Gastritis and postural hypotension. Patient also taking other drugs - Efexor XR, Olanzapine, Omeprazole, Temaze and Sodium Valproate. Patient has been treated with clozapine since April 1996.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 181000 **Seq:** 1
Reported: 23/12/2002
Hospitalisation: Admitted to hospital
Onset Date: 26/08/2002
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 31
DOB: 17/02/1971
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Pneumonia and T wave inversion worsening.	Treated with iv antibiotics and oxygen.
Electrocardiogram T wave inversio	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet 300.0 Milligram Daily Oral

Batch: **Started:** 29/07/2002 **Stopped:** 28/08/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/12/2002	Electrocardiograph				

Additional Information:

Historical condition - Electrocardiogram T wave inversion.

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 183041 **Seq:** 1 **Gender:** F
Reported: 20/12/2002 **Weight:** 0.00
Hospitalisation: **Age:** 29
Onset Date: **DOB:** 04/05/1973
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Epilepsy		The patient experienced an epileptic fit.	Clozaril ceased

Medicine Details:

CLOZARIL (Suspected) **Reason:**
Tablet 12.5 Milligram Daily Oral
Batch: **Started:** **Stopped:** 06/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2001 To 31 Dec 2002 Unclear causality excluded GM medicines Only Tradenames: CLOPINE,CLOZAPINE,CLOZARIL

Report Details:

Case Number: 184111 **Seq:** 1
Reported: 10/12/2002
Hospitalisation: Admitted to hospital
Onset Date: 17/10/2002
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 38
DOB: 10/09/1964
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Anxiety Delusional disorder, mixed type Psychotic disorder Suicidal ideation		Patient experienced exacerbation of psychosis with symptoms of anxiety, being suicidal and delusional.	

Medicine Details:

CLOZARIL (Suspected) **Reason:** Unspecified schizophrenia

Tablet	600.0 Milligram	Daily	Oral	
Batch:	**Started:** 18/08/1998		**Stopped:**	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History - The patient had SCH 130 PHRENA with intrusive perceptual disturbances. The patient had received Clozaril in the past during 2002, without developing simlar symptoms. Clozaril was re-challenged without any adverse event.