



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 147634 **Seq:** 1 **Gender:** F
Reported: 04/01/2000 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			Zoloft dose reduced to

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



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Report Detail

Case Number: 147635 **Seq:** 1 **Gender:** M
Reported: 04/01/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Agitation			Zoloft ceased, dose of zyprexa increased to 15mg/day.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 147638

Seq: 1

Gender: M

Reported: 04/01/2000

Weight:

Hospitalisation:

Age: 21Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Deafness Otosclerosis Tinnitus		Hearing loss in the right ear.	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1999	Stopped: 28/12/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Audiogram suggests otosclerosis - no family history.

Additional Information:

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



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Report Detail

Case Number: 147653 **Seq:** 1 **Gender:** F
Reported: 05/01/2000 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: 10/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epistaxis			

Medicine Details:

DOXYCYCLINE HYDROCHLORIDE (Suspected)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started: 10/12/1999	Stopped: 17/12/1999	
ZOLOFT (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Report Detail

Case Number: 147841

Seq: 1

Gender: M

Reported: 10/01/2000

Weight:

Hospitalisation:

Age: 60Y

Onset Date: 31/12/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 147868 **Seq:** 1 **Gender:** F
Reported: 10/01/2000 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rectal haemorrhage			

Medicine Details:

ZOLOFT (Suspected)	Reason: Obsessive compulsive neurosis
Batch:	Started: 0.0 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient with a previous history of rectal bleeding, found that his recurred after starting zoloft. - the date of onset is not accurate but indicates that onset occurred sometime during the year.



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Report Detail

Case Number: 147909 **Seq:** 1 **Gender:** F
Reported: 12/01/2000 **Weight:**
Hospitalisation: **Age:** 41Y
Onset Date: 17/07/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Colitis		Severe diarrhoea	Given salazopine.

Medicine Details:

MINULET (Other drug)	Reason: Contraception
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason:
50.0 Milligram Daily	
Batch:	Started: 10/06/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Colonoscopy showed colonic inflammation on biopsy 08/99.

Additional Information:



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Report Detail

Case Number: 147984 **Seq:** 1 **Gender:** F
Reported: 13/01/2000 **Weight:**
Hospitalisation: **Age:** 17Y
Onset Date: 31/01/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Patient found to have significantly elevated	No action taken.

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started: 05/01/2000	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 147985 **Seq:** 1 **Gender:** M
Reported: 13/01/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Patient has developed tremor.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 148028 **Seq:** 1 **Gender:** F
Reported: 18/01/2000 **Weight:** 54.00
Hospitalisation: **Age:** 34Y
Onset Date: 23/11/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder Tremor Headache Hyperacusis Visual disturbance		Severe drug induced parkinsonism Upper and lower limb tremor	

Medicine Details:

HALDOL DECANOATE (Suspected)	Reason:
25.0 Milligram Fortnightly Batch: Started: 30/10/1999 Stopped:	
SERTRALINE HYDROCHLORIDE (Suspected)	Reason: Depression
Tablet 150.0 Milligram Daily Oral Batch: Started: 23/11/1999 Stopped: 26/11/1999	
LITHIUM CARBONATE (Suspected)	Reason: Depression
530.0 Milligram Daily Batch: Started: 12/11/1999 Stopped: 25/11/1999	
BENZTROPINE MESYLATE (Suspected)	Reason:
2.0 Milligram Daily Batch: Started: 13/11/1999 Stopped: 26/11/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Report Detail

Case Number: 148028

Seq: 1

Gender: F

Reported: 18/01/2000

Weight: 54.00

Hospitalisation:

Age: 34Y

Onset Date: 23/11/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

NICOTINE TRANSDERMAL PATCH (Suspected)

Reason:

Cream

10.0 Milligram

Daily

Transdermal

Batch:

Started: 03/11/1999

Stopped:

Laboratory Investigations:

Additional Information:



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Report Detail

Case Number: 148129

Seq: 1

Gender: M

Reported: 19/01/2000

Weight: 60.00

Hospitalisation:

Age: 15Y

Onset Date: 31/12/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrasystoles			
Palpitations			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason:
25.0 Milligram	Daily
Batch:	Started: 01/01/1999
	Stopped: 31/01/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrographics				Multiple unifocal ventricular ectopics.

Additional Information:

Patient also taking dexamphetamine and clonidine. previously no cardio vascular history. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage stop date is not accurate but indicates that stoppage occurred sometime during the year.



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Report Detail

Case Number: 148171

Seq: 1

Gender: F

Reported: 17/01/2000

Weight:

Hospitalisation:

Age: 70Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Nausea			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	reason:	Depression
Tablet	50.0 Milligram	Daily
Batch:	Started:	Stopped: 1W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Report Detail

Case Number: 148189

Seq: 1

Gender: U

Reported: 20/01/2000

Weight:

Hospitalisation:

Age:

Onset Date: 10/01/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Ceased sertraline

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking timentin, span k, gliclazide, g-csf, nystatin, digoxin and perindopril.



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Report Detail

Case Number: 148236 **Seq:** 1 **Gender:** F
Reported: 20/01/2000 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 10/01/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Severe exacerbation of generalised	Prednisolone

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 03/01/2000 Stopped: 10/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Report Detail

Case Number: 148273

Seq: 1

Gender: U

Reported: 24/01/2000

Weight:

Hospitalisation:

Age:

Onset Date: 31/12/1999

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Tremor			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason: Unspecified psychosis
50.0 Milligram	Daily
Batch:	Started: 01/11/1998
	Stopped: 28/11/1998

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



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Report Detail

Case Number: 148274 **Seq:** 1 **Gender:** F
Reported: 24/01/2000 **Weight:**
Hospitalisation: **Age:** 86Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			Zoloft reduced

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Batch:	Started:	Stopped:	0.0
ZOLOFT (Suspected)		Reason: Depression	
Batch:	Started:	Stopped:	50.0 Milligram Daily

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 148275 **Seq:** 1 **Gender:** F
Reported: 24/01/2000 **Weight:**
Hospitalisation: **Age:** 9Y
Onset Date: 31/01/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			
Insomnia			

Medicine Details:

ZOLOFT (Suspected)	Reason: Obsessive compulsive neurosis
12.5 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 148276

Seq: 1

Gender: M

Reported: 24/01/2000

Weight:

Hospitalisation:

Age: 23Y

Onset Date: 31/12/1999

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sleep disorder		Pt sleeping during the day and not at night.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



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Report Detail

Case Number: 148277

Seq: 1

Gender: M

Reported: 24/01/2000

Weight:

Hospitalisation:

Age: 38Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			Zoloft reduced to 50mg/day.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: Stopped: 3W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Report Detail

Case Number: 148297 **Seq:** 1 **Gender:** F
Reported: 24/01/2000 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 31/01/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania Agitation Neurosis		Hypomania	It is planned to reduce the dose of zoloft.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 148298 **Seq:** 1 **Gender:** F
Reported: 24/01/2000 **Weight:**
Hospitalisation: **Age:** 78Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Ceased zoloft.

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started:	Stopped:
		4W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 148299 **Seq:** 1 **Gender:** M
Reported: 24/01/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 13Y
Onset Date: 31/12/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression Drug ineffective Suicide attempt			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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Report Detail

Case Number: 148344 **Seq:** 1 **Gender:** M
Reported: 27/01/2000 **Weight:** 86.00
Hospitalisation: **Age:** 58Y
Onset Date: 18/08/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder Thinking abnormal Agitation Mydriasis Psychotic disorder		Pressured speech Thoughts disordered/bizaar ideas	Ceased zoloft and continued on bupropion

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 01/01/1998 Stopped: 20/08/1999
PSEUDOEPHEDRINE NOS (Suspected)	Reason: Ac upr resp inf,mult,unsp stes
360.0 Milligram Daily	
Batch:	Started: 17/08/1999 Stopped: 20/08/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history of depression. possible bipolar disorder. no definate history of previous psychosis. the dosage start date is not accurate but indicates that start occurred sometime during the year.



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Report Detail

Case Number: 148352 **Seq:** 1 **Gender:** M
Reported: 28/01/2000 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 31/10/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 01/10/1999 Stopped: 28/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Lft's deteriorated further when dose doubled. improved when stopped. with change of treatment to cipramil (seq 02 - 148353) deteriorated again with more symptoms. much improved on nothing. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148360

Seq: 1

Gender: F

Reported: 27/01/2000

Weight: 76.00

Hospitalisation:

Age: 40Y

Onset Date: 31/05/1998

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy Libido decreased Anorgasmia		Aversion --> disinterest in being touched Complete disinterest in sex	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 01/05/1998
	Stopped: 10/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft was ceased and resulted in withdrawal reaction (see seq 02 - 148361). - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148361

Seq: 1

Gender: F

Reported: 27/01/2000

Weight: 76.00

Hospitalisation:

Age: 40Y

Onset Date: 10/01/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			
Drug withdrawal syndrome			
Nausea			
Nervousness			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 01/05/1998
	Stopped: 10/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Initial reaction to zoloft (see seq 01 - 148360) resulted in ceasing zoloft. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148363 **Seq:** 1 **Gender:** F
Reported: 27/01/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 01/10/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148364 **Seq:** 1 **Gender:** F
Reported: 27/01/2000 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			Plans to discontinue doxepin

Medicine Details:

ZOLOFT (Interaction)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: Stopped:
DOXEPIN HYDROCHLORIDE (Interaction)	Reason: Otr&unsp vertebrogen pain synd
10.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148417

Seq: 1

Gender: F

Reported: 31/01/2000

Weight: 55.00

Hospitalisation:

Age: 44Y

Onset Date: 23/01/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Rash: itchy, blotchy, red on neck arms	
Pruritus			Telfast

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	100.0 Milligram
	Daily
	Oral
Batch:	Started: 14/01/2000
	Stopped: 25/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148448 **Seq:** 1 **Gender:** F
Reported: 31/01/2000 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 25/01/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Dizziness			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 15/01/2000 Stopped: 25/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148449

Seq: 1

Gender: F

Reported: 31/01/2000

Weight:

Hospitalisation:

Age: A8

Onset Date: 31/12/1998

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaemia			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
0.0	
Batch:	Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148451

Seq: 1

Gender: F

Reported: 31/01/2000

Weight:

Hospitalisation:

Age: 58Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
Tablet	50.0 Milligram	Daily
Batch:	Started:	Stopped:
		1W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt also taking rocaltrol and diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148500

Seq: 1

Gender: F

Reported: 01/02/2000

Weight: 73.00

Hospitalisation:

Age: AD

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	09/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148691

Seq: 1

Gender: M

Reported: 08/02/2000

Weight:

Hospitalisation:

Age: 54

Onset Date:

DOB: 08/05/1945

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Hypomanic reaction	Ceased sertraline. given lithium carbonate 500mg bd.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason: Depression
300.0 Milligram	Daily
Batch:	Started: 01/09/1999
	Stopped: 28/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148771 **Seq:** 1 **Gender:** F
Reported: 07/02/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 85Y
Onset Date: 24/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Hyponatraemia			Discontinue sertraline and substitute with moclobemide. previous supplemented na+ via iv infusion

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 01/12/1999	Stopped: 30/12/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chloride	100-110	25/12/1999	84	
	Chloride	100-110	27/12/1999	84	
	Chloride	100-110	28/12/1999	83	
	Chloride	100-110	29/12/1999	79	
	Electrolytes	5-15	25/12/1999	8	Anion gap.
	Electrolytes	5-15	27/12/1999	7	Anion gap.
	Electrolytes	5-15	29/12/1999	12	Anion gap.

Additional Information:

Patient also taking lisinopril, diazepam, dexamethasone, aspirin and maxolon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148771 Seq: 1

Gender: F

Reported: 07/02/2000

Weight:

Hospitalisation: Admitted to hospital

Age: 85Y

Onset Date: 24/12/1999

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/12/1999	Stopped: 30/12/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes	5-15	28/12/1999	9	Anion gap.
	Potassium	3.2-4.5	25/12/1999	4.3	
	Potassium	3.2-4.5	27/12/1999	4.0	
	Potassium	3.2-4.5	29/12/1999	3.1	
	Potassium	3.2-4.5	28/12/1999	3.2	
	Sodium	135-145	25/12/1999	118	
	Sodium	135-145	27/12/1999	117	

Additional Information:

Patient also taking lisinopril, diazepam, dexamethasone, aspirin and maxolon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148771 Seq: 1

Gender: F

Reported: 07/02/2000

Weight:

Hospitalisation: Admitted to hospital

Age: 85Y

Onset Date: 24/12/1999

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/12/1999	Stopped: 30/12/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	135-145	28/12/1999	120	
	Sodium	135-145	29/12/1999	118	
	bicarbonate	22-33	25/12/1999	26	
	bicarbonate	22-33	27/12/1999	26	
	bicarbonate	22-33	28/12/1999	28	
	bicarbonate	22-33	29/12/1999	27	

Additional Information:

Patient also taking lisinopril, diazepam, dexamethasone, aspirin and maxolon.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 148999

Seq: 1

Gender: M

Reported: 14/02/2000

Weight: 65.00

Hospitalisation:

Age: 62Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation disorder		Sensation of blockage when ejaculates.	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 05/01/1998	Stopped: 17/01/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149162 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Electroencephalogram abnormal	Severe	Patient experienced a severe tonic clonic	Sertralin ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electroencephalog				Eeg showed marked abnormality with multiple paroxysms of sharp/spike and slow was complexes predominantly over right mid to posterior areas, particularly over the temporal region, and at times bilaterally synchronous one neurological review, it was considered the eeg findings were consistent with a post-ictal disturbance, rather than the development of epilepsy per se.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149166

Seq: 1

Gender: F

Reported: 16/02/2000

Weight: 60.00

Hospitalisation:

Age: 80

Onset Date: 10/02/2000

DOB: 05/07/1919

Outcome: Recovered

Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Jacksonian (focal) epilepsy.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 04/02/2000
	Stopped: 10/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking dilantin, zestril, indepamide and ranitidine. patient history: similar episode 4/12 ago 1/52 after commencing sertraline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149175 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 10Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Insomnia Mania			Zoloft discontinued.

Medicine Details:

ZOLOFT (Suspected)	Reason: Obsessive compulsive neurosis
Tablet	12.5 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149176

Seq: 1

Gender: U

Reported: 16/02/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cerebral haemorrhage Syncope			

Medicine Details:

ZOLOFT (Interaction)		Reason:	
Tablet	0.0	Daily	Oral
Batch:	Started:	Stopped:	
WARFARIN SODIUM (Interaction)		Reason:	
Tablet	0.0	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This event occurred 3 to 4 years ago.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149179 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 50Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			Zolof was discontinued and then re-started at a smaller dose
Hyperhidrosis			
Mania			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started to become hypomanic and zolof was withdrawn rapidly over 3-4 days. - the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149182

Seq: 1

Gender: M

Reported: 16/02/2000

Weight:

Hospitalisation:

Age: 63Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysuria			
Nephrolithiasis			
Urinary tract infection			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking lasix, ventolin, atrovent, beconase, losec, panafcort- elone, steroids eg.prednisolone, aminophylline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149187 **Seq:** 1 **Gender:** M
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** A6
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			Zoloft was discontinued

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft was discontinued and changed to another antidepressant, without success. patient has again commenced zoloft as prefers to have depression successfully treated. - the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149188 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 52Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy skin	Zoloft was discontinued

Medicine Details:

ZOLOFT (Suspected)	Reason:		
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	4D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149190 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 54Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Severe nausea	Ceased zoloft

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	2D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after first day of taking zoloft. - the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149191 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia		Lockjaw	Ceased zoloft.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
	0.0 Milligram 5 times
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient previously experienced same symptoms while on amitriptyline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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Report Detail

Case Number: 149192 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			Ceased zoloft

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on zoloft therapy, for a total of about 6 months had dose increased to 600mg/day and developed symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149194 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 31/01/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Single migraine headache	Zoloft discontinued.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1999	Stopped:	28/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149195 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: 31/01/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus Drug withdrawal syndrome Insomnia Nausea		Itch all body.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 01/11/1999 Stopped: 28/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149197 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: 31/12/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle contractions involuntary		Teeth chattering and muscle jerks.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Anxiety neurosis
50.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is under some additional stress at the moment. patient has been on zoloft 50mg/day for 6 months and 100mg dose for 12 months. - the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149198 **Seq:** 1 **Gender:** F
Reported: 16/02/2000 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Chronic cough	Zoloft dose reduced.
Hyperhidrosis		Night sweats	
Flushing			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 01/01/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149432 **Seq:** 1 **Gender:** F
Reported: 21/02/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 14/02/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Rash all over body.	Loratadine

Medicine Details:

KEFLEX (Suspected)		Reason:	
Oral application	3.0 Dose Unspecified Daily	Oral	
Batch:	Started: 02/02/2000	Stopped:	09/02/2000
ZOLOFT (Suspected)		Reason:	
Tablet	1.0 Dose Unspecified Daily	Oral	
Batch:	Started: 02/02/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking aropax, temaze, aureomycin oint.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149453 **Seq:** 1 **Gender:** M
Reported: 21/02/2000 **Weight:**
Hospitalisation: **Age:** A2
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Patient began to suffer bad headaches.	Patient was recommenced on 50mg zoloft (sertraline).
Drug withdrawal syndrome			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	8M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred after patient abruptly stopped taking zoloft. he was recommenced at 50mg with the intentions of gradually tapering off zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149455 **Seq:** 1 **Gender:** F
Reported: 21/02/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Patient had excessive sweating.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149763

Seq: 1

Gender: M

Reported: 29/02/2000

Weight: 60.00

Hospitalisation:

Age: 31

Onset Date:

DOB: 19/11/1968

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bruxism		Patient grinds his teeth.	
Yawning			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: L TERM
	Stopped: 16/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is still clenching teeth on efexor but much less severe.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149921

Seq: 1

Gender: M

Reported: 03/03/2000

Weight: 130.00

Hospitalisation:

Age: 60Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis Mania Salivary hypersecretion			Zoloft discontinued and the patient was started on

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149925 **Seq:** 1 **Gender:** F
Reported: 02/03/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 28Y
Onset Date: 24/02/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Abdominal pain Diarrhoea Malaise Peripheral ischaemia Tetany Vomiting		Patient experienced paraesthesia in her	2mg cogentin, supportive treatment. 1.5gm of calcium

Medicine Details:

ZOLOFT (Suspected)	Reason:
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: 24/02/2000 Stopped: 24/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been hyperventilating. fingers became contorted.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149952

Seq: 1

Gender: M

Reported: 03/03/2000

Weight: 85.00

Hospitalisation:

Age: 69Y

Onset Date: 02/02/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Imodium
Rash erythematous			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 02/11/1999	Stopped: 16/02/2000	
STELAZINE (Suspected)		Reason: Depression	
	2.0 Milligram	Daily	
Batch:	Started: 26/11/1999	Stopped: 09/02/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149975 **Seq:** 1 **Gender:** F
Reported: 03/03/2000 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms each time zoloft dose was increased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149976

Seq: 1

Gender: F

Reported: 03/03/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of 10kg.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149977

Seq: 1

Gender: U

Reported: 03/03/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Excessive sweating	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149978

Seq: 1

Gender: F

Reported: 03/03/2000

Weight:

Hospitalisation:

Age: 30Y

Onset Date: 31/12/2000

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149980 **Seq:** 1 **Gender:** M
Reported: 03/03/2000 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			Zolft was discontinued.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149981 **Seq:** 1 **Gender:** F
Reported: 03/03/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 58Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Headache Orthostatic hypotension Vomiting			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet 25.0 Milligram Daily Oral	
Batch: Started: Stopped: 3D	
ZOLOFT (Suspected)	Reason: Depression
Tablet 50.0 Milligram Daily Oral	
Batch: Started: Stopped: 2D	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was initially taking 25mg zoloft for 3 days and developed symptoms, the dose was increased to 50mg and patient suffered further symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 149986 **Seq:** 1 **Gender:** F
Reported: 03/03/2000 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Severe agitation	Patient was commenced on 100mg/day dose of zoloft and experienced symptoms, dose of zoloft was reduced to 50mg/day, was later increased to 75mg/day without problems.
Anxiety		Severe anxiety.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150028

Seq: 1

Gender: M

Reported: 06/03/2000

Weight: 75.00

Hospitalisation:

Age: 59

Onset Date: 20/12/1999

DOB: 28/11/1940

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Severe itch	
Paraesthesia		Subjective heat forearms.	
Hyperhidrosis			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 01/01/1998
	Stopped: 17/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking metohexal, tritace, lescol, astrix. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150086

Seq: 1

Gender: F

Reported: 08/03/2000

Weight: 65.00

Hospitalisation:

Age: 42Y

Onset Date: 20/02/2000

DOB:

Outcome: Recovered

Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Faecal incontinence Diarrhoea		Incontinence 5 time per day with no	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 15/02/2000
	Stopped: 24/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took zoloft 100mg/day from 7.12.99 to 15.2.00. rechallenged with zoloft 100mg/day on 010300 with return of diarrhoea.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150133 **Seq:** 1 **Gender:** M
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 36Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase incr			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =				Ggt levels three times above normal.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150134 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokalaemia Hyponatraemia Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Electrolytes				Hypokalaemia (3.2 mmol/l), hyponatraemia (120mmol/l)

Additional Information:

Patient also taking thyroxine, norvasc, brimonadine eye drops, xalatan.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150136 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 59Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Headache Orthostatic hypotension Vomiting			Zoloft ceased

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	1W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150178 **Seq:** 1 **Gender:** F
Reported: 10/03/2000 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 26/11/1999 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gout			

Medicine Details:

ZOLOFT (Suspected)	Reason:
0.0	
Batch:	Started: 14/11/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking actrapid, avapro, azathioprine, frusemide, losec, norfloxacin, premarin, protaphane. commenced zolof and within two weeks experienced symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150194

Seq: 1

Gender: F

Reported: 09/03/2000

Weight:

Hospitalisation:

Age: 44Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Patient experienced profuse sweating.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking hormone replacement therapy - not specified.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150196 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue		Patient complained of tiredness and feeling	Zoloft ceased.
Dizziness		Patient felt dizzy.	
Nausea		Patient felt nauseous.	

Medicine Details:

STELAZINE (Other drug)		Reason: Unspecified schizophrenia	
	0.0		
Batch:	Started:		Stopped:
ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150198 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Severe	Patient experienced severe diarrhoea.	Zoloft ceased after three weeks therapy.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	3W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150199 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Patient has experienced sweating.	None.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150200 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Patient experienced inc. propensity for	None.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been taking zoloft for 1 month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150202 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Severe	Patient has been suffering from severe	None.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on zoloft for approximately three months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150203 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			None.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
		100.0 Milligram	Daily
Batch:	Started:	S TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on zoloft for 12 months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150205 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			Zoloft ceased and patient switched back to amitriptylline.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
50.0 Milligram		Daily	
Batch:	Started:	Stopped:	5D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been on amitriptylline for ten years, but was switched to zoloft after an unspecified washout period.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150206 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** A2
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Patient has experienced anxiety.	None.
Palpitations		Patient has experienced palpitations.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150207

Seq: 1

Gender: F

Reported: 09/03/2000

Weight:

Hospitalisation:

Age: 84Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Patient experienced ongoing nausea.	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on zoloft for 10 days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150208

Seq: 1

Gender: M

Reported: 09/03/2000

Weight:

Hospitalisation:

Age:

Onset Date: 31/12/1999

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Patient developed headaches.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	6W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150209 **Seq:** 1 **Gender:** M
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash vesicular		Patient developed rash.	Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed rash, a couple of weeks after commencing zoloft. patient thought it was a heat rash and kept taking zoloft. eventually rash became very itchy, big red blotches like psoriasis with some raised vesicles developed mainly around body folds eg. under arms, inside elbow.



THERAPEUTIC GOODS ADMINISTRATION
Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150210 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	1W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient developed rash first on back of the neck then moving around to front and spreading.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150212 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 65Y
Onset Date: 01/02/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue		Patient experienced excessive lethargy.	
Somnolence		Patient experienced excessive sleepiness.	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	3D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150213 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 82Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Patient developed somatization disorder.	Zoloft discontinued.
Anxiety			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of suicidal inclinations.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150214 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare			

Medicine Details:

ZOLOFT (Suspected)		Reason: Anxiety neurosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150215 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea Hyperprolactinaemia			None.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	300.0 Milligram Daily Oral
Batch:	Started: 01/10/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150216 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** A5
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Malaise Headache Tremor		Patient developed withdrawal syndrome. Patient feeling unwell.	Reinitiation of zoloft 50mg

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 01/08/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions occurred one week after ceasing zoloft. patient had been on zoloft for 18m before ceasing. initially patient was on 50mg daily, then 100mg daily. reduced dose to 50mg daily before ceasing medication. symptoms resolved a week after reinitiation of zoloft 50mg daily. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150217 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150218 **Seq:** 1 **Gender:** M
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 31/12/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150219 **Seq:** 1 **Gender:** F
Reported: 09/03/2000 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: 18/02/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary tract infection		Patient also developed uti.	Zoloft ceased. uti was treated with trimethoprim.
Coordination abnormal		Patient experienced ataxia.	
Gait disturbance		Patient experienced gait abnormalities.	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression
	50.0 Milligram	Daily
Batch:	Started:	Stopped: 18/02/2000 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been on zoloft 50mg daily a month before starting on 100mg zoloft. patient also taking diamicon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150425 **Seq:** 1 **Gender:** M
Reported: 15/03/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 80
Onset Date: 07/03/2000 **DOB:** 07/06/1919
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Confusional state Delirium			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started:	05/03/2000
	Stopped:	08/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking sinement, insulin actrapid, gliclazide and diamicon.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150514

Seq: 1

Gender: F

Reported: 21/03/2000

Weight: 70.00

Hospitalisation:

Age: 46Y

Onset Date: 24/02/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Biliary colic			
Hepatic function abnormal			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 11/05/1999
	Stopped: 25/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT AST = SGOT GGT = SGGT = Immunology LDH SAP = ALP				Alt 615. Ast 204. Ggt 360. Viral serology was (n) (no ehv a/b/c, ebv nor cmv). Ld 261. Alp 146.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150540 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 48Y
Onset Date: 31/12/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Severe	Patient felt ill immediately, with severe	Patient hospitalised, zoloft discontinued.
Malaise		Patient was acutely unwell.	
Diarrhoea	Severe	Severe diarrhoea.	
Serotonin syndrome			

Medicine Details:

ZOLOFT (Interaction)		Reason: Depression
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 3D
AURORIX (Interaction)		Reason: Depression
	600.0 Milligram	Daily
Batch:	Started:	Stopped: 2W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Moclobemide was discontinued, and after a 1 week washout period, commenced zoloft 25mg/day. reactions then occurred. - the date of onset is not accurate but indicates that onset occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150541

Seq: 1

Gender: M

Reported: 21/03/2000

Weight:

Hospitalisation:

Age: 26Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Patient's death by suicide in late 1999.	
Drug ineffective			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/02/1999	Stopped: 28/03/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Date of death: 3/1999. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150542

Seq: 1

Gender: F

Reported: 21/03/2000

Weight:

Hospitalisation:

Age: 45Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced an "epileptic fit".	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	3M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had no history of epilepsy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150617 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: 31/01/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			Imipramine

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150619 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 55Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Agitation Anxiety Insomnia			Zoloft ceased

Medicine Details:

ZOLOFT (Suspected)	Reason:	Anxiety neurosis
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 3D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt discontinued oxazepam without a tapering off period and without washout, and commenced on zoloft 50mg/d.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150620

Seq: 1

Gender: F

Reported: 21/03/2000

Weight:

Hospitalisation:

Age: A6

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Loperamide and metronidazole

Medicine Details:

ZOLOFT (Suspected)	Reason:
50.0 Milligram	Daily
Batch:	Started: 01/01/2000
	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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150621 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: 25/02/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Exacerbate the patient anxiety	
Conversion disorder			Zoloft ceased
Drug ineffective			

Medicine Details:

ZOLOFT (Suspected)	Reason: Anxiety neurosis
100.0 Milligram	Daily
Batch:	Started: 20/02/2000 Stopped: 25/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150622

Seq: 1

Gender: M

Reported: 21/03/2000

Weight:

Hospitalisation:

Age: 19Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Not able to get out of bed in the morning	Zoloft reduced to 25mg and changed time of dosing.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 01/11/1999
	Stopped: 28/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150623 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 39Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Including teeth gnashing and leg jerking at	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150625 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 20Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope			Zoloft ceased

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150627

Seq: 1

Gender: F

Reported: 21/03/2000

Weight:

Hospitalisation:

Age: 48Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorgasmia			
Libido decreased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150629 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased			

Medicine Details:

GINSENG (Interaction)		Reason:	
Oral application	0.0		Oral
Batch:	Started:		Stopped:
VITAMIN B COMPLEX (Interaction)		Reason:	
Oral application	0.0		Oral
Batch:	Started:		Stopped:
ZOLOFT (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced vit b complex and ginseng, and complained that the zoloft no longer seemed to be as effective.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150632 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Isordil ceased.

Medicine Details:

ISORDIL (Suspected)		Reason:	
Oral application	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150687 **Seq:** 1 **Gender:** F
Reported: 21/03/2000 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 10/03/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Heart disease congenital			Major surgery.

Medicine Details:

FEFOL (Suspected)		Reason:	
Capsule	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped:	
BLACKMORES PREGNANCY AND BREAST-FEEDING FORMULA (Suspected)		Reason:	
Capsule	2.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ALDOMET (Suspected)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Transposition of the greater vessels of the heart.

Additional Information:

5 other siblings in family. one brother born to a different father has tuberous sclerosis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150687

Seq: 1

Gender: F

Reported: 21/03/2000

Weight:

Hospitalisation:

Age: 31Y

Onset Date: 10/03/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

CARDIPRIN 100 (Suspected)

Reason:

Tablet

100.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

5 other siblings in family. one brother born to a different father has tuberous sclerosis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150737

Seq: 1

Gender: M

Reported: 24/03/2000

Weight: 78.00

Hospitalisation:

Age: 71Y

Onset Date: 09/02/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension		Bp up from 120/80 to 195/120.	
Tachycardia		Heart pounding	Oral frusemide 80mg, ramipril
Dizziness			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram
Batch:	Daily
	Oral
	Started: 08/02/2000
	Stopped: 09/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced zoloft on 8/2/00 with loading dose of 100mg to be followed by 50mg, 2 hours after 50mg dose patient experienced symptoms. patient was also taking sotacor, proscar, solprin, deptran.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150775 **Seq:** 1 **Gender:** F
Reported: 27/03/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 01/01/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Malaise Nausea			Recommended 25mg zoloft.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms resolved after zoloft is reintroduced.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150778 **Seq:** 1 **Gender:** F
Reported: 27/03/2000 **Weight:**
Hospitalisation: **Age:** A5
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety		Patient felt anxious.	Zoloft was ceased.
Tremor		Patient was shaky.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150779

Seq: 1

Gender: U

Reported: 27/03/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Patient developed an uncomplicated fine	

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
Tablet	100.0 Milligram	Daily
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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150780 **Seq:** 1 **Gender:** F
Reported: 27/03/2000 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Pt experienced nausea while on 25mg, 50mg & 75mg.	
Hepatic function abnormal			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Biochemistry				Ggt and alt approx 100 and 60 respectively, a few weeks after

Additional Information:

Nausea subsided after each dosage increase.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150797 Seq: 1

Gender: F

Reported: 27/03/2000

Weight: 70.00

Hospitalisation:

Age: 40

Onset Date: 19/03/2000

DOB: 27/02/1960

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne		Facial rash with multiple pustules.	Ceased zoloft.

Medicine Details:

ZOLOFT (Suspected)				Reason:	Depression
Tablet	50.0	Milligram	Daily		Oral
Batch:	Started:	08/03/2000	Stopped:	22/03/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient did not previously have acne.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150826 **Seq:** 1 **Gender:** F
Reported: 27/03/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 21Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dehydration Diarrhoea Syncope Vomiting			Iv fluids were given and zoloft was discontinued.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft was reintroduced and the symptoms returned. patient was on zoloft for a total of 4 days.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150835

Seq: 1

Gender: F

Reported: 27/03/2000

Weight: 0.00

Hospitalisation:

Age: 15Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tourette's disorder Tic		Tics due to Tourette's syndrome were	

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
Batch:	2.0 Milligram	Daily	Stopped:
ZOLOFT (Suspected)		Reason: Depression	
Batch:	25.0 Milligram	Daily	Oral
Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 150836 **Seq:** 1 **Gender:** F
Reported: 27/03/2000 **Weight:**
Hospitalisation: **Age:** 84Y
Onset Date: 24/02/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erythema multiforme			Ceased zoloft and risperidone.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
RISPERIDONE (Suspected)		Reason: Unspecified psychosis
Tablet	1.0 Milligram	Daily Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150893 **Seq:** 1 **Gender:** M
Reported: 28/03/2000 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 21/03/2000 **DOB:** 24/04/1961
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Agitation Depersonalisation Insomnia		"to end it all". Patient felt agitated and driven. Patient felt strange and not himself.	Required a visit to doctor. counselling and alprazolam 0.25mg tds

Medicine Details:

TAZAC (Other drug)		Reason:	
	600.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 21/03/2000	Stopped: 23/03/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No prior use of antidepressants.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150998

Seq: 1

Gender: F

Reported: 28/03/2000

Weight: 84.00

Hospitalisation:

Age: 56

Onset Date:

DOB: 31/10/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic cirrhosis	Severe	Severe cirrhosis of liver.	Tamoxifen ceased.

Medicine Details:

TAMOXIFEN CITRATE (Suspected)		Reason: Malignant neoplasm of breast	
Tablet	0.0	Daily	Oral
Batch:	Started:	L TERM	Stopped:
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped:	
FOSINOPRIL (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped:	
ALLOPURINOL (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 150998

Seq: 1

Gender: F

Reported: 28/03/2000

Weight: 84.00

Hospitalisation:

Age: 56

Onset Date:

DOB: 31/10/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PRAVASTATIN SODIUM (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1996	Stopped: 04/02/2000	
ISOSORBIDE MONONITRATE (Suspected)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1997	Stopped:	

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151064 **Seq:** 1 **Gender:** M
Reported: 28/03/2000 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 29/11/1999 **DOB:** 15/07/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased Convulsion Hyperpyrexia Hyperreflexia Hypertonia			Dilantin tds ivi, acyclovir ivi (hsv possible) 500mg tds x 4 doses. zoloft (sertraline ceased).

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression
100.0 Milligram	Daily	
Batch:	Started: 26/11/1999	Stopped: 29/11/1999
LITHIUM CARBONATE (Suspected)		Reason:
Tablet	1.5 Gram Daily	Oral
Batch:	Started:	Stopped: 02/12/1999
THIORIDAZINE HYDROCHLORIDE (Suspected)		Reason: Otr spec symp psychopathol nec
100.0 Milligram	Daily	
Batch:	Started: 27/11/1999	Stopped: 29/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine		26/11/1999	73	
	Creatine		03/12/1999	2515	

Additional Information:

Serotonin syndrome most probable neuroleptic malignant syndrome.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151079

Seq: 1

Gender: F

Reported: 31/03/2000

Weight: 56.00

Hospitalisation:

Age: 44

Onset Date: 03/03/2000

DOB: 30/08/1955

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dermatitis bullous		Blistering rash neck, chest, forearms,	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 24/02/2000 Stopped: 09/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking 33 se, vitamin c, garlic and licorice, erythropoietin, calcium and magnesium.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151193

Seq: 1

Gender: F

Reported: 03/04/2000

Weight:

Hospitalisation:

Age: A7

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

ZOLOFT (Suspected)					Reason:		Depression	
Tablet		50.0 Milligram		Daily		Oral		
Batch:		Started:		S TERM		Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has been taking zoloft for a period of 2 months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151211

Seq: 1

Gender: F

Reported: 27/03/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache Muscle twitching Nausea			Naproxen.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
TRYPTOPHAN (Suspected)		Reason:	
Oral application	1.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151267 **Seq:** 1 **Gender:** U
Reported: 05/04/2000 **Weight:**
Hospitalisation: **Age:** 43
Onset Date: 17/03/2000 **DOB:** 12/05/1956
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing Diarrhoea Dry mouth Headache Insomnia Malaise Nightmare Palpitations Pollakiuria		Severe flushing	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After 2 days initiation of zoloft patient experienced symptoms. pethidine -nausea.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151413 **Seq:** 1 **Gender:** U
Reported: 10/04/2000 **Weight:**
Hospitalisation: **Age:** 45
Onset Date: **DOB:** 15/08/1954
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cardiac disorder		Abnormal routine echocardiogram.	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	700.0 Milligram Daily Oral
Batch:	Started: 01/01/1995 Stopped: CONTIN
SERTRALINE HYDROCHLORIDE (Suspected)	Reason:
	150.0 Milligram Daily
Batch:	Started: Stopped:
ATENOLOL (Suspected)	Reason:
	50.0 Milligram Daily
Batch:	Started: Stopped:
ATORVASTATIN (Suspected)	Reason:
	20.0 Milligram Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiology				Mild dilated lv and mild decrease in systolic function, apex hypokinesia. ie. lv dysfunction.

Additional Information:

Patient also has hypertension and there is a strong family history of cardiac disease. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151423

Seq: 1

Gender: M

Reported: 10/04/2000

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		"pins & needles" across all of body.	
Hypertension		170-180/110 mm hg.	
Muscle twitching		Muscle twitching in calves and shoulders.	None.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft given for obsessive compulsive disorder. patient has been on zoloft for 4 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151425 **Seq:** 1 **Gender:** M
Reported: 10/04/2000 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 01/03/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			None.

Medicine Details:

ZOLOFT (Suspected)		Reason: Anxiety neurosis	
		25.0 Milligram	Daily
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred two weeks after starting zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151460 **Seq:** 1 **Gender:** M
Reported: 10/04/2000 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations			Zoloft was reduced from 50mg to 25mg daily.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151461 **Seq:** 1 **Gender:** F
Reported: 10/04/2000 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: 21/03/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Rash consisting of pin point red spots.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151462 **Seq:** 1 **Gender:** F
Reported: 10/04/2000 **Weight:**
Hospitalisation: **Age:** 10Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Micturition disorder			Reduced zoloft to 3/4 of a 50mg tablet.

Medicine Details:

ZOLOFT (Suspected)		Reason: Obsessive compulsive neurosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151463 **Seq:** 1 **Gender:** F
Reported: 10/04/2000 **Weight:**
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms 6 months after starting zoloft 50mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151465

Seq: 1

Gender: F

Reported: 10/04/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

Reason: Depression			
0.0			
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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151503

Seq: 1

Gender: F

Reported: 11/04/2000

Weight: 70.00

Hospitalisation:

Age: 53

Onset Date: 04/04/2000

DOB: 30/10/1946

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Nausea			
Vomiting			Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred within 4 hours of having zoloft therapy. patient also taking - ogen, lipitor, karvea and norvasc.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151555

Seq: 1

Gender: F

Reported: 12/04/2000

Weight:

Hospitalisation:

Age: 26Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania		Increase in manic symptoms.	
Hypoaesthesia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151556 **Seq:** 1 **Gender:** F
Reported: 12/04/2000 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 02/04/2000 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrointestinal haemorrhage		Gastrointestinal bleed (haemorrhagic	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
INDOCID (Suspected)		Reason:	
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died 4/4/00. patient had been a reformed alcoholic for the past 6 months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151565 **Seq:** 1 **Gender:** F
Reported: 11/04/2000 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence neonatal			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby of lactating mother was noticed to be sleeping for 9 hours per day without waking for milk.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151575 **Seq:** 1 **Gender:** M
Reported: 12/04/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151576

Seq: 1

Gender: F

Reported: 12/04/2000

Weight:

Hospitalisation:

Age: 32Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Exacerabation of nausea & vomitng due to pregnancy	
Vomiting			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151577 **Seq:** 1 **Gender:** F
Reported: 12/04/2000 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

LOSEC (Other drug)		Reason:	
	0.0		
Batch:	Started:		Stopped:
ASPIRIN (Other drug)		Reason:	
	0.0		
Batch:	Started:		Stopped:
ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151578 **Seq:** 1 **Gender:** U
Reported: 12/04/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura		Bleeding into skin-red blotches.	
Nausea		Severe nausea	
Dizziness			

Medicine Details:

ZOLOFT (Suspected)		Reason: Anxiety neurosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recently had an allergic reaction to 1/2 a paroxetine tablet.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151580 **Seq:** 1 **Gender:** M
Reported: 12/04/2000 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Nightmare			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after ceasing zoloft. patient was on 100mg, dose was reduced to 50mg for 1 week and then ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151581

Seq: 1

Gender: M

Reported: 12/04/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia			Zoloft was reduced to 50mg from 100mg daily.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151583 **Seq:** 1 **Gender:** F
Reported: 12/04/2000 **Weight:**
Hospitalisation: **Age:** A4
Onset Date: 28/03/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue Asthenia		Severe lethargy	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	1 time	Oral
Batch:	Started: 28/03/2000	Stopped:	28/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after taking one 50mg zoloft tablet.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 151803 **Seq:** 1 **Gender:** M
Reported: 17/04/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 12/03/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Prednisone.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had an allergic rash which predates the use of nortriptyline.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152053

Seq: 1

Gender: M

Reported: 26/04/2000

Weight:

Hospitalisation:

Age: 40Y

Onset Date: 12/04/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue		Lethargy while being on zoloft for one week	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152054 **Seq:** 1 **Gender:** F
Reported: 26/04/2000 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukocytosis			Zoloft ceased
Leukocytosis			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced similar reaction while on paroxetine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152055

Seq: 1

Gender: F

Reported: 26/04/2000

Weight:

Hospitalisation:

Age: A6

Onset Date: 10/04/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence		Patient slept for 3 days after taking one	Zoloft ceased

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	1W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152056

Seq: 1

Gender: F

Reported: 26/04/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular			Zoloft ceased

Medicine Details:

ZOLOFT (Suspected)	reason:	Depression
Tablet	50.0 Milligram	Daily
Batch:	Started:	Stopped: 1W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152057 **Seq:** 1 **Gender:** F
Reported: 26/04/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152061 **Seq:** 1 **Gender:** F
Reported: 26/04/2000 **Weight:**
Hospitalisation: **Age:** 16Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Twitching of muscles of shoulders and	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred four years after starting zoloft therapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152062 **Seq:** 1 **Gender:** M
Reported: 26/04/2000 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Severe		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152063 **Seq:** 1 **Gender:** F
Reported: 26/04/2000 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Metrorrhagia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152064 **Seq:** 1 **Gender:** F
Reported: 26/04/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Dizziness Headache Myalgia		Breathlessness	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced the following symptoms while scuba diving.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152065 **Seq:** 1 **Gender:** M
Reported: 26/04/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152066 **Seq:** 1 **Gender:** F
Reported: 26/04/2000 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorgasmia			Zoloft ceased
Breast pain			

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	2M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152118

Seq: 1

Gender: M

Reported: 28/04/2000

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Persistent diarrhoea	Ceased aoloft and commenced cipramil.

Medicine Details:

ZOLOFT (Suspected)	reason:	Depression
Tablet	100.0 Milligram	Daily
Batch:	Started:	Stopped:
		2M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152119 **Seq:** 1 **Gender:** M
Reported: 28/04/2000 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 11/04/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			Reduced zoloft from 50mg to

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152120 **Seq:** 1 **Gender:** F
Reported: 28/04/2000 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			Zoloft reduced from 100mg to 50mg daily.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152122

Seq: 1

Gender: U

Reported: 28/04/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152123

Seq: 1

Gender: U

Reported: 28/04/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152124 **Seq:** 1 **Gender:** F
Reported: 28/04/2000 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152125

Seq: 1

Gender: U

Reported: 28/04/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152278

Seq: 1

Gender: M

Reported: 02/05/2000

Weight:

Hospitalisation:

Age: 41Y

Onset Date: 13/01/1999

DOB:

Outcome: Death

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

TEGRETOL (Suspected)		Reason:	Depression
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 29/12/1998	Stopped: 13/01/1999	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	Depression
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 29/12/1998	Stopped: 13/01/1999	
DIAZEPAM (Suspected)		Reason:	
Oral application	5.0 Milligram	Daily	Oral
Batch:	Started: 29/12/1998	Stopped: 13/01/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Pharmacokinetics				At autopsy, the patient's stomach and blood contents indicated therapeutic levels of administered drugs. cause of death unspecified

Additional Information:

Hypertension, coronary atherosclerosis, and aggravated by stress were regarded as possible contributory factors. patient had an enlarged liver from alcohol over use earlier in life, and also hypertension which was managed by gp for 2-3 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152363 **Seq:** 1 **Gender:** F
Reported: 04/05/2000 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Deafness		Hearing impairment.	

Medicine Details:

AVAPRO (Suspected)	Reason:
0.0	
Batch:	Started: 01/01/1999 Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
SERTRALINE HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152386

Seq: 1

Gender: F

Reported: 05/05/2000

Weight: 55.00

Hospitalisation:

Age: 38

Onset Date: 01/04/2000

DOB: 03/03/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 01/09/1999
	Stopped: 01/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152483 **Seq:** 1 **Gender:** M
Reported: 08/05/2000 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itch increased.	
Pain		Limited movement	
Skin exfoliation		Skin started to peel on palms of hands.	
Hypokinesia			
Psoriasis			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	4W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms while taking zoloft for 4 weeks.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152495 **Seq:** 1 **Gender:** F
Reported: 10/05/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** A8
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			
Orthostatic hypotension			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms a couple weeks after starting zoloft. patient recovered and re-initiated on zoloft, no problems so far.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152501 **Seq:** 1 **Gender:** F
Reported: 10/05/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 72Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability Anxiety Drug withdrawal syndrome Hyperhidrosis		Crying and felt terrible. Increased anxiety	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking valium and mogadon. patient ceased zoloft on his own accord. seven days later developed symptoms. zoloft was restarted without any great improvement.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152510

Seq: 1

Gender: M

Reported: 10/05/2000

Weight:

Hospitalisation:

Age: 40Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after 1 week of zoloft therapy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152511 **Seq:** 1 **Gender:** F
Reported: 10/05/2000 **Weight:**
Hospitalisation: **Age:** A5
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Aching feet	
Drug withdrawal syndrome			
Muscle spasms			

Medicine Details:

ZOLOFT (Suspected)	Reason:
100.0 Milligram	Daily
Batch:	Started: 01/01/1998 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms one week after stopping zoloft three weeks ago. restarted zoloft on 3/5/00 and symptoms improved. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152622 **Seq:** 1 **Gender:** F
Reported: 15/05/2000 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	100.0 Milligram	Daily
Batch:	Started:	Stopped: 6W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced worsening of parkinsonian symptoms after dose of zoloft was increased to 100mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152634

Seq: 1

Gender: M

Reported: 15/05/2000

Weight:

Hospitalisation:

Age: 26Y

Onset Date: 15/04/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Severity of headache to that of migraine	Ceased sertraline

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 15/04/2000
	Stopped: 01/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced severe symptoms when dose of sertraline was increased from 25mg to 50mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152636

Seq: 1

Gender: F

Reported: 15/05/2000

Weight: 40.00

Hospitalisation:

Age: 60Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

ZOLOFT (Suspected)	Reason:		
Tablet	25.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after one dose of 25mg zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152770

Seq: 1

Gender: M

Reported: 16/05/2000

Weight: 97.00

Hospitalisation:

Age: 43

Onset Date: 06/04/2000

DOB: 03/12/1956

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain		Body pain	
Headache		Extreme headache	Zoloft stopped. required a visit to doctor.
Nausea			

Medicine Details:

ZOLOFT (Suspected)	Reason:
50.0 Milligram	Daily
Batch:	Started: 04/04/2000
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: days of work. still no recovery. patient also taking coversyl, lipitor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152788

Seq: 1

Gender: F

Reported: 19/05/2000

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Experienced staccato speech.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced staccato speech when starting zoloft, problem beginning to subside. has been on zoloft for 6 months so far. now on 100mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152789 **Seq:** 1 **Gender:** F
Reported: 19/05/2000 **Weight:**
Hospitalisation: **Age:** 6Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Outbursts of temper.	
Anxiety			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152791 **Seq:** 1 **Gender:** F
Reported: 19/05/2000 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Generalized aching	
Asthenia		Muscle weakness	Zoloft ceased.
Headache			

Medicine Details:

ZOLOFT (Suspected)	Reason: Anxiety neurosis
Tablet	25.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Had been on amitryptilline 50mg for 1 week 36hrs before starting zoloft.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152825 **Seq:** 1 **Gender:** F
Reported: 22/05/2000 **Weight:**
Hospitalisation: **Age:** 61
Onset Date: **DOB:** 09/09/1938
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Normochromic normocytic anaemia			

Medicine Details:

UREX (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
TEMAZE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ATIVAN (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
COVERSYL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				The marrow shows erythroid hyperplasia and in the presence of a falling haemoglobin and normal reticulocyte count in the peripheral blood suggests inadequate marrow response to presumed blood loss or haemolysis. there is no evidence of marrow aplasia, infiltration or underlying myelodysplasia

Additional Information:

Symptoms occurred in June 1999, 6 months after commencing therapy with aredia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152825

Seq: 1

Gender: F

Reported: 22/05/2000

Weight:

Hospitalisation:

Age: 61

Onset Date:

DOB: 09/09/1938

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PANADEINE FORTE (Suspected)			Reason:
	0.0		
Batch:	Started:		Stopped:
FENTANYL CITRATE (Suspected)			Reason:
	0.0		
Batch:	Started:		Stopped:
ZOLOFT (Suspected)			Reason:
	0.0		
Batch:	Started:		Stopped:
ZOTON (Suspected)			Reason:
	0.0		
Batch:	Started:		Stopped:

Laboratory Investigations:

Additional Information:

Symptoms occurred in June 1999, 6 months after commencing therapy with aredia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152825

Seq: 1

Gender: F

Reported: 22/05/2000

Weight:

Hospitalisation:

Age: 61

Onset Date:

DOB: 09/09/1938

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

LIPITOR (Suspected)		Reason:	
Batch:	Started:	Stopped:	
AREDIA (Suspected)		Reason: Malignant neoplasm of breast	
Injection, intravenous infusion	90.0 Milligram	Daily	Intravenous
Batch:	Started: 01/01/1999	Stopped:	CONTIN

Laboratory Investigations:

Additional Information:

Symptoms occurred in June 1999, 6 months after commencing therapy with aredia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152865

Seq: 1

Gender: F

Reported: 23/05/2000

Weight: 57.00

Hospitalisation:

Age: 50Y

Onset Date: 15/05/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Nightsweats.	
Headache		Retroorbital headache.	
Nausea			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 15/05/2000	Stopped: 15/05/2000	
LIPITOR (Suspected)		Reason: Othr&unspec metabolic diseases	
	10.0 Milligram	Daily	
Batch:	Started: 13/04/2000	Stopped: 15/05/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

H/o: migraine but this dissimilar headache. patient also taking klovance.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 152867 **Seq:** 1 **Gender:** F
Reported: 23/05/2000 **Weight:**
Hospitalisation: **Age:** 51Y
Onset Date: 12/05/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion Drug withdrawal syndrome Amnesia Confusional state Dizziness		Mouth-watering. Two days after stopping zoloft 25mg.	Reinitiated zoloft.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	25.0 Milligram Daily Oral
Batch:	Started: Stopped: 10/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on 100mg for 3 months, then 50mg for 3 months and then 25mg. patient also taking hrt - not specified.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153031 **Seq:** 1 **Gender:** F
Reported: 22/05/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 25/02/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia Rhinitis Drug withdrawal syndrome neonatal Nervousness		Lip smacking, extensor posturing, jerky Sneezy from 28/2/00-01/3/00.	Baby was given iv antibiotics, gentamicin, penicillin, 24 hours post delivery then stop.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression
	200.0 Milligram	Daily
Batch:	Started: L TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

1 day old male baby suffered symptoms after delivery, mother taking sertraline mother now breast feeding and still taking sertraline, dose reduced to 175mg post delivery with plan for further reduction. nil adverse effects reported in infant as result of breast feeding. baby recovered 28/2/00.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153044

Seq: 1

Gender: F

Reported: 25/05/2000

Weight:

Hospitalisation:

Age: 48Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Involuntary movements of tongue.	Zolof ceased.

Medicine Details:

ZOLOFT (Suspected)				Reason:	Depression
Tablet	50.0	Milligram	Daily		Oral
Batch:	Started:	19/02/1999	Stopped:	21/01/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153094

Seq: 1

Gender: F

Reported: 25/05/2000

Weight: 48.00

Hospitalisation:

Age: 41

Onset Date: 12/05/2000

DOB: 04/01/1959

Outcome: Recovered

Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Hyperkinesia Insomnia Tremor			Required visit to a doctor

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took two doses. same reaction occurred each time and lasted 12-18 hrs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153101 **Seq:** 1 **Gender:** M
Reported: 25/05/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Seeing flashing light, while decreasing	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153102 **Seq:** 1 **Gender:** F
Reported: 25/05/2000 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Abdominal bloating and pain.	
Myalgia		Muscle aches.	
Fatigue			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	25.0 Milligram	Alternate days	Oral
Batch:	Started:	L TERM	Stopped: 28/02/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on zoloft for two and half years at 50mg/d reduced to 25mg/d and then 25mg/alternate days. 6 months ago, zoloft was ceased in a similar fashion and patient experienced abdominal bloating and pain. zoloft was subsequently reinitiated. patient also taking - atrovent. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153116 **Seq:** 1 **Gender:** U
Reported: 26/05/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerks	
Hyperkinesia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is taking zoloft 100mg or 200mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153125 **Seq:** 1 **Gender:** M
Reported: 26/05/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia			
Urinary retention			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking amiodorine and beta blocker (not specific). history of atrial fibrillation and prostatism.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153133 **Seq:** 1 **Gender:** F
Reported: 26/05/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 22/05/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Dizziness on 4th day of treatment.	

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 18/05/2000	Stopped:	22/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153179 **Seq:** 1 **Gender:** F
Reported: 19/05/2000 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153183

Seq: 1

Gender: M

Reported: 26/05/2000

Weight:

Hospitalisation:

Age: 30Y

Onset Date: 09/05/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Azoospermia		Low sperm count	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153240 **Seq:** 1 **Gender:** F
Reported: 31/05/2000 **Weight:**
Hospitalisation: Treated in outpatient department only. **Age:** 25Y
Onset Date: 22/05/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced a seizure.	Treated in a&e but not admitted. advised to consult

Medicine Details:

SALAZOPYRIN (Suspected)		Reason: Other rheumatoid arthritis	
Tablet	4.0 Dose Unspecified	Daily	Oral
Batch:	Started: 01/04/2000	Stopped:	CONTIN
PREDNISOLONE (Suspected)		Reason:	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2000	Stopped:	CONTIN
ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/06/1999	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has no personal history of seizures but her sister has had one seizure. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153242

Seq: 1

Gender: M

Reported: 31/05/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Myalgia		Neck and muscle cramps	
Dystonia			

Medicine Details:

INTERFERON ALFA-2A (Suspected)		Reason:	Other diseases of liver	
Injection	0.0		Intravenous	
Batch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	Depression	
Tablet	100.0 Milligram	Daily	Oral	
Batch:	Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has been on zoloft for 10 weeks so far.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153243

Seq: 1

Gender: F

Reported: 31/05/2000

Weight:

Hospitalisation:

Age: 87Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Renal impairment		Elevation in serum creatinine	Zoloft and losec ceased.

Medicine Details:

LOSEC (Suspected)		Reason:	
Oral application	0.0		Oral
Batch:	Started: 01/04/2000	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/03/2000	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. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153308 **Seq:** 1 **Gender:** F
Reported: 31/05/2000 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido increased		Vaginal & clitoral engorgement & need to	Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction started 24-36 hours after initiation of zoloft and subsided a few days after zoloft ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153309 **Seq:** 1 **Gender:** M
Reported: 31/05/2000 **Weight:**
Hospitalisation: **Age:** 59Y
Onset Date: 01/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain		Abdominal pains for 3-4 weeks	Ceased zoloft and changed to another ssri.
Nausea		Nausea for 3-4 weeks.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Solution	50.0 Millilitre Daily Oral
Batch:	Started: 01/04/2000 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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153310 **Seq:** 1 **Gender:** F
Reported: 31/05/2000 **Weight:**
Hospitalisation: **Age:** 14Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Vomiting			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153375 **Seq:** 1 **Gender:** M
Reported: 01/06/2000 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Palpitations		Palpitations and irregular heartbeat.	Ceased zoloft.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153376 **Seq:** 1 **Gender:** F
Reported: 01/06/2000 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Zoloft ceased and aripiprazole

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153377

Seq: 1

Gender: F

Reported: 01/06/2000

Weight:

Hospitalisation:

Age: 23Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Infertility female		Difficulty in becoming pregnant.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was treated with zoloft 50mg daily from the ages of 17 to 20. dose would occasionally be increased to 100mg daily to correspond with menstrual cycle.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153381 **Seq:** 1 **Gender:** F
Reported: 06/06/2000 **Weight:**
Hospitalisation: **Age:** 68Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			
Fatigue			
Myalgia			

Medicine Details:

IPRATROPIUM BROMIDE (Other drug)		Reason:
Inhalation	0.0	Inhalation
Batch:	Started:	Stopped:
ZOLOFT (Suspected)		Reason:
Tablet	0.0	Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been on zoloft for 2.5 years at 50mg/day. reduced this to 25mg/day and then to 25mg on alternate days. zoloft ceased in feb 2000. one week ago patient developed symptoms which seem to have improved over week. 6 months ago, zoloft was ceased in similar fashion and patient experienced abdominal bloating, pain, zoloft was subsequently reinitiated.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153423

Seq: 1

Gender: F

Reported: 05/06/2000

Weight: 55.00

Hospitalisation:

Age:

Onset Date: 14/05/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Yawning		Constant yawning.	Zoloft ceased of patients own
Dyspnoea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Started dose at 1/2 a tablet daily for 5 days with no reaction and no effect. increased to 1 tablet daily with immediate reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153442 **Seq:** 1 **Gender:** F
Reported: 05/06/2000 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		2 weeks after increasing zoloft to 100mg.	Bromocriptine commenced and the zoloft dose was reduced to 50mg.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Examination revealed that the patient did not have a pituitary adenoma.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153496 **Seq:** 1 **Gender:** F
Reported: 08/06/2000 **Weight:**
Hospitalisation: **Age:** 87Y
Onset Date: 11/05/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Renal impairment			

Medicine Details:

LOSEC (Suspected)	Reason: Other diseases of esophagus
20.0 Milligram Daily	
Batch:	Started: 21/03/2000 Stopped: 16/05/2000
ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 15/02/2000 Stopped: 16/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT		23/12/1999	-	
	ALT = SGPT		11/05/2000	180	
	AST = SGOT		23/12/1999	-	
	AST = SGOT		11/05/2000	111	
	Creatinine		23/12/1999	0.11	
	Creatinine		11/05/2000	0.23	
	Creatinine		25/05/2000	0.16	

Additional Information:

Patient also taking adalat, astrix. since cessation of both drugs lft's have returned to normal and creatinine has improved to 0.16 mmol/l.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153496

Seq: 1

Gender: F

Reported: 08/06/2000

Weight:

Hospitalisation:

Age: 87Y

Onset Date: 11/05/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

LOSEC (Suspected)	20.0 Milligram	Daily	Reason: Other diseases of esophagus
Batch:	Started: 21/03/2000	Stopped: 16/05/2000	
ZOLOFT (Suspected)	50.0 Milligram	Daily	Reason: Depression
Batch:	Started: 15/02/2000	Stopped: 16/05/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP		23/12/1999	-	
	SAP = ALP		11/05/2000	139	

Additional Information:

Patient also taking adalat, astrix. since cessation of both drugs lft's have returned to normal and creatinine has improved to 0.16 mmol/l.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153781

Seq: 1

Gender: F

Reported: 14/06/2000

Weight: 65.00

Hospitalisation:

Age: 30

Onset Date: 31/10/1999

DOB: 28/10/1969

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities Intra-uterine death		Dandy walker syndrome.	Delivery at 5 months - still born

Medicine Details:

DIAZEPAM (Suspected)		Reason:	
	20.0 Milligram	Weekly	
Batch:	Started:	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/07/1999	Stopped: 28/11/1999	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pregnancy with congenital abnormality - dandy walker syndrome. sertraline stopped at 3 weeks gestation. delivery at 5 months - still born foetus. no known allergies. not previously taken this indication. using approx. 20mg diazepam per week at that time - was on oral contraceptive pill? omitted 1 or 2 tabs. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153900

Seq: 1

Gender: F

Reported: 16/06/2000

Weight: 95.00

Hospitalisation:

Age: 68

Onset Date:

DOB: 25/11/1931

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Rash and pruritus 4 weeks after starting	Required a visit to doctor.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking inderal, prednisolone, spironolactone, temazepam, losec, plaquenil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153903 **Seq:** 1 **Gender:** F
Reported: 16/06/2000 **Weight:** 65.00
Hospitalisation: **Age:** 39
Onset Date: 13/06/2000 **DOB:** 28/06/1960
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gingival hyperplasia	Required Specialist Consultation		

Medicine Details:

ZOLOFT (Suspected)	Reason: Anxiety neurosis
100.0 Milligram	Daily
Batch:	Started: 12/11/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 153992 **Seq:** 1 **Gender:** F
Reported: 21/06/2000 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Hyperkinesia Serotonin syndrome Choreoathetosis Dystonia Hyperhidrosis Nausea Palpitations Pruritus		Extremely anxious and agitated. Legs were moving involuntarily. Serotonergic reaction.	

Medicine Details:

ALCOHOL (Suspected)		Reason:	
Oral application	20.0 Gram	Total	Oral
Batch:	Started:	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154082 **Seq:** 1 **Gender:** F
Reported: 26/06/2000 **Weight:**
Hospitalisation: **Age:** 15Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Facial twisting, grimacing and frowning	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1999	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred 18 months after starting clozaril. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154140 **Seq:** 1 **Gender:** M
Reported: 23/06/2000 **Weight:**
Hospitalisation: **Age:** 57
Onset Date: 01/06/2000 **DOB:** 07/08/1942
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Herpes simplex		3 eruptions of hsv on buttock	

Medicine Details:

FAMVIR (Other drug)	Reason:
500.0 Milligram	Daily
Batch:	Started: 01/01/1998 Stopped:
ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 27/05/2000 Stopped: 02/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 15/6/00. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154176 **Seq:** 1 **Gender:** F
Reported: 23/06/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Increase of olanzapine & became verbally	
Drug withdrawal syndrome		Sertraline was being withdrawn at the time.	

Medicine Details:

ZYPREXA (Suspected)		Reason:	
	30.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
ZOLOFT (Suspected)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154201 **Seq:** 1 **Gender:** F
Reported: 26/06/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Severe		Dose of zoloft reduced to

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms occurred during the first 7 days of therapy with zoloft. zoloft dose was reduced from 50mg/d to 25mg/d.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154274

Seq: 1

Gender: F

Reported: 28/06/2000

Weight: 65.00

Hospitalisation:

Age: 35Y

Onset Date: 25/05/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Day long headache	
Nausea		Nausea took 3 weeks to settle.	Stopped zoloft
Vertigo		Vertigo within 3 weeks after stopping zoloft.	
Drug withdrawal syndrome			

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started: 15/03/2000	Stopped: 15/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154297

Seq: 1

Gender: M

Reported: 29/06/2000

Weight:

Hospitalisation:

Age: 78

Onset Date: 14/06/2000

DOB: 11/04/1922

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Truncal and facial rash.	

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 08/06/2000	Stopped: 14/06/2000	
CELEBREX (Suspected)		Reason: Unspecified arthritis	
	400.0 Milligram	Daily	
Batch:	Started: 01/06/2000	Stopped: 14/06/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking rastinon, pravastatin, solprin and endone. zoloff recommenced without problem.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154393 **Seq:** 1 **Gender:** F
Reported: 01/07/2000 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dental caries		Increase in tooth decay, required 15 fillings.	
Dry mouth			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 01/07/1997 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous history of cavities. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154671

Seq: 1

Gender: F

Reported: 10/07/2000

Weight: 55.00

Hospitalisation:

Age: 49

Onset Date: 31/03/1999

DOB: 14/10/1949

Outcome: Recovered

Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Inner ear disorder		Acute labyrinthitis when off zoloft for 4	Continue zoloft.
Drug withdrawal syndrome			

Medicine Details:

ZOLOFT (Suspected)	Reason:
0.0	
Batch:	Started: 01/10/1998
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has restarted and stopped slowly three times and same symptoms recur. has recovered now as long as she continues zoloft. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154719 **Seq:** 1 **Gender:** M
Reported: 12/07/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 83Y
Onset Date: 04/07/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Duodenal ulcer Melaena			Ceased celebrex and aspirin. omeprazole given.

Medicine Details:

CELEBREX (Suspected)	Reason: Osteoarthritis
200.0 Milligram Daily Batch: Started: 08/06/2000 Stopped: 05/07/2000	
ASPIRIN (Suspected)	Reason: Acute, ill-def cerebrovascular disease w/o hyperten
150.0 Milligram Daily Batch: Started: 01/01/1995 Stopped: 05/07/2000	
SERTRALINE HYDROCHLORIDE (Suspected)	Reason: Depression
50.0 Milligram Daily Batch: Started: 01/06/2000 Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Haemoglobin		23/06/2000	159	Endoscopy showed severe ulcerative duodenitis, with two chronic duodenal ulcers and evidence of recent bleed.
	Haemoglobin		05/07/2000	114	
	Other data				

Additional Information:

Patient was also taking amlodipine, telmisartan. no history of peptic ulcer disease/gord. has not taken nsaid's previously. the dosage start date is not accurate but indicates that start occurred sometime during the year. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 154746

Seq: 1

Gender: M

Reported: 13/07/2000

Weight: 98.00

Hospitalisation:

Age: 46

Onset Date: 13/05/2000

DOB: 20/11/1953

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Electric shocks	Taking about <25mg to stop symptoms for 1.5 days.
Depersonalisation			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 19/11/1998
	Stopped: 12/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Smoking marijuana also stops the symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155109 **Seq:** 1 **Gender:** F
Reported: 20/07/2000 **Weight:**
Hospitalisation: **Age:** 79Y
Onset Date: 13/03/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Sertraline ceased. fluid

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		03/03/2000	138	
	Sodium		06/03/2000	132	
	Sodium		08/03/2000	136	
	Sodium		13/03/2000	126	
	Sodium		15/03/2000	125	
	Sodium		16/03/2000	127	
	Sodium		17/03/2000	130	

Additional Information:

Patient also taking metformin, heparin, carbamazepine, paracetamol, digoxin, gliclazide, nystatin, frusemide, isosorbide mononitrate sr, perindopril, spironolactone and omeprazole.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155109

Seq: 1

Gender: F

Reported: 20/07/2000

Weight:

Hospitalisation:

Age: 79Y

Onset Date: 13/03/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		18/03/2000	131	
	Sodium		20/03/2000	129	
	Sodium		22/03/2000	131	
	Sodium		23/03/2000	137	
	Sodium		27/03/2000	134	
	Sodium		30/03/2000	130	
	Sodium		10/04/2000	133	

Additional Information:

Patient also taking metformin, heparin, carbamazepine, paracetamol, digoxin, gliclazide, nystatin, frusemide, isosorbide mononitrate sr, perindopril, spironolactone and omeprazole.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155110

Seq: 1

Gender: F

Reported: 20/07/2000

Weight:

Hospitalisation:

Age: 78Y

Onset Date: 31/03/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 03/03/2000	Stopped: 07/04/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT	<40	25/02/2000	37	
	ALT = SGPT	<40	22/03/2000	44	
	ALT = SGPT	<40	27/03/2000	523	
	ALT = SGPT	<40	14/04/2000	32	
	ALT = SGPT	<40	08/04/2000	44	
	AST = SGOT	<35	25/02/2000	36	
	AST = SGOT	<35	27/03/2000	267	

Additional Information:

Patient also taking vitamin compound, zoton, coversyl, coloxyl with senna, olanzapine and panadine. previous adr's: sodium valproate - nausea, propantheline (jan 00 - 3.3.00 inducing delirium. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155110

Seq: 1

Gender: F

Reported: 20/07/2000

Weight:

Hospitalisation:

Age: 78Y

Onset Date: 31/03/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 03/03/2000	Stopped: 07/04/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	AST = SGOT	<35	22/03/2000	23	
	AST = SGOT	<35	08/04/2000	23	
	AST = SGOT	<35	14/04/2000	14	
	Bilirubin	<20	25/02/2000	15	
	Bilirubin	<20	22/03/2000	8	
	Bilirubin	<20	27/03/2000	11	
	Bilirubin	<20	08/04/2000	7	

Additional Information:

Patient also taking vitamime compound, zoton, coversyl, coloxyl with senna, olanzapine and panadine. previous adr's: sodium valproate - nausea, propantheline (jan 00 - 3.3.00 inducing delerium. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155110

Seq: 1

Gender: F

Reported: 20/07/2000

Weight:

Hospitalisation:

Age: 78Y

Onset Date: 31/03/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 03/03/2000	Stopped: 07/04/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Bilirubin	<20	14/04/2000	7	
	GGT = SGGT =	<50	25/02/2000	22	
	GGT = SGGT =	<50	22/03/2000	76	
	GGT = SGGT =	<50	08/04/2000	127	
	GGT = SGGT =	<50	14/04/2000	87	
	GGT = SGGT =	<50	27/03/2000	329	
	SAP = ALP	30-120	25/02/2000	80	

Additional Information:

Patient also taking vitamin compound, zoton, coversyl, coloxyl with senna, olanzapine and panadine. previous adr's: sodium valproate - nausea, propantheline (jan 00 - 3.3.00 inducing delirium. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155110

Seq: 1

Gender: F

Reported: 20/07/2000

Weight:

Hospitalisation:

Age: 78Y

Onset Date: 31/03/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 03/03/2000	Stopped: 07/04/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	SAP = ALP	30-120	22/03/2000	119	
	SAP = ALP	30-120	27/03/2000	278	
	SAP = ALP	30-120	08/04/2000	152	
	SAP = ALP	30-120	14/04/2000	129	

Additional Information:

Patient also taking vitamin compound, zoton, coversyl, coloxyl with senna, olanzapine and panadine. previous adr's: sodium valproate - nausea, propantheline (jan 00 - 3.3.00 inducing delirium. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155128 **Seq:** 1 **Gender:** F
Reported: 20/07/2000 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: 01/01/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1999	Stopped:	04/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum osmolality	270-290	24/09/1999	280	
	Serum osmolality	270-290	01/01/2000	249	
	Serum osmolality	270-290	02/01/2000	245	
	Serum osmolality	270-290	04/01/2000	257	
	Serum osmolality	270-290	08/01/2000	265	
	Serum osmolality	270-290	06/01/2000	261	
	Serum osmolality	270-290	03/01/2000	250	

Additional Information:

Patient also taking coloxyl with senna, fgf, thyroxine, aspirin, zantac, risperdal and rocaltrol. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155128

Seq: 1

Gender: F

Reported: 20/07/2000

Weight:

Hospitalisation:

Age: 83Y

Onset Date: 01/01/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1999	Stopped: 04/01/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	135-145	24/09/1999	138	
	Sodium	135-145	01/01/2000	121	
	Sodium	135-145	02/01/2000	120	
	Sodium	135-145	03/01/2000	124	
	Sodium	135-145	04/01/2000	121	
	Sodium	135-145	06/01/2000	126	
	Sodium	135-145	08/01/2000	130	

Additional Information:

Patient also taking coloxyl with senna, fgf, thyroxine, aspirin, zantac, risperdal and rocaltrol. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155334

Seq: 1

Gender: F

Reported: 21/07/2000

Weight: 60.00

Hospitalisation:

Age: 32

Onset Date: 16/05/2000

DOB: 17/09/1967

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Dizziness Dry mouth Malaise		Stiffness in r leg and weakness	Date of recovery 18/05/00

Medicine Details:

ZOLOFT (Suspected)	Reason: Anxiety neurosis
50.0 Milligram	Daily
Batch:	Started: 15/05/2000
	Stopped: 16/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had a cva affecting right side in 1995.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155398 **Seq:** 1 **Gender:** F
Reported: 24/07/2000 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 18/07/2000 **DOB:** 06/12/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Skin is red	
Pain		Sore skin	Required a visit to doctor.

Medicine Details:

MARVELON (Other drug)		Reason: Contraception
Tablet	0.0	Oral
Batch:	Started:	Stopped:
ZOLOFT (Suspected)		Reason: Depression
Tablet	0.0	Oral
Batch:	Started: 10/07/2000	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155517 **Seq:** 1 **Gender:** F
Reported: 27/07/2000 **Weight:**
Hospitalisation: **Age:** 99
Onset Date: 02/03/2000 **DOB:** 20/12/1900
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft ceased, plan to change to meclizemide.

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	25.0 Milligram	Daily
Batch:	Started:	Stopped: 02/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium			128.	

Additional Information:

Patient also taking spiractin, senekot, panamax and sorbilax. date of recovery 3.3.00.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155573 **Seq:** 1 **Gender:** F
Reported: 28/07/2000 **Weight:**
Hospitalisation: **Age:** 36
Onset Date: 16/07/2000 **DOB:** 30/09/1963
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash		Starting on abdo.	
Pruritus			

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	25.0 Milligram	Daily
Batch:	Started:	13/07/2000
	Stopped:	18/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: other ssri - nausea.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 155625

Seq: 1

Gender: F

Reported: 31/07/2000

Weight: 60.00

Hospitalisation:

Age: 43

Onset Date:

DOB: 03/10/1956

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Marked depression on cessation of zoloft.	Required a visit to doctor.
Drug withdrawal syndrome		Onset depression within 6 weeks of	

Medicine Details:

ZOLOFT (Suspected)		Reason: Anxiety neurosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 18/06/1996	Stopped:	28/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has no previous history of depression. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156015 **Seq:** 1 **Gender:** F
Reported: 09/08/2000 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Dyskinesia		Baby having frequent episodes of leg Mouth grimacing.	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 07/06/2000	Stopped:	13/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby 5 mts old. patient breast feeding. after 30 days on zolofit noticed baby having frequent episodes of leg stiffening and mouth grimacing. zolofit was stopped on 13/07/00, baby movements reduced considerably, but didn't completely stopped. recommenced zolofit on 20/07/00, baby movements increased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156020 **Seq:** 1 **Gender:** F
Reported: 09/08/2000 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: 27/07/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction)		Reason: Depression
Oral application	0.0	Oral
Batch:	Started:	Stopped:
CLOZARIL (Interaction)		Reason: Unspecified schizophrenia
Tablet	650.0 Milligram	Daily Oral
Batch:	Started: 01/01/1995	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level		27/07/2000	1672NG/ML	Clozapine plasma levels

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156285 **Seq:** 1 **Gender:** M
Reported: 14/08/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 56
Onset Date: 11/07/2000 **DOB:** 29/06/1944
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Leukaemia		Lymphoblastic leukaemia	

Medicine Details:

CLOZARIL (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 02/07/1999	Stopped:	
ZOLOFT (Suspected)		Reason:	
	100.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156295

Seq: 1

Gender: M

Reported: 14/08/2000

Weight: 72.00

Hospitalisation:

Age: 23

Onset Date: 08/08/2000

DOB: 26/01/1977

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Dizziness Headache Vomiting			Metoclopramide 10mg po. required a visit to doctor.

Medicine Details:

NALTREXONE HYDROCHLORIDE (Suspected)	Reason:
50.0 Milligram Daily	
Batch:	Started: 09/08/2000
ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 09/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

H/o alcohol dependency. reaction started within 12 hrs starting naltrexone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156437

Seq: 1

Gender: M

Reported: 15/08/2000

Weight: 100.00

Hospitalisation:

Age: 42Y

Onset Date: 15/06/2000

DOB:

Outcome: Recovered

Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Rash on legs, face arms.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 15/06/2000
	Stopped: 20/06/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous exposure to zoloft produced same reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156445

Seq: 1

Gender: F

Reported: 15/08/2000

Weight: 64.00

Hospitalisation:

Age: 65

Onset Date: 20/07/2000

DOB: 14/12/1934

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Left side of head pins/needles.	
Rash pustular		Pimples on scalp	
Anxiety			Zoloft stopped. required a visit to doctor. date of recovery 01/08/00
Headache			

Medicine Details:

ZOLOFT (Suspected)	Reason:
Tablet	50.0 Milligram
	Daily
	Oral
Batch:	Started: 20/07/2000
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking premarin, provera, fgf, sotacor, zantac.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156565 **Seq:** 1 **Gender:** F
Reported: 21/08/2000 **Weight:** 0.00
Hospitalisation: **Age:** 38
Onset Date: 20/07/2000 **DOB:** 26/09/1961
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased Cardiomegaly Drug level increased Hepatic cirrhosis Pneumonia Sudden death			

Medicine Details:

MESASAL (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
SERTRALINE HYDROCHLORIDE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
CALTRATE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
RANITIDINE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/12/2002	Biochemistry				
17/12/2002	Histology				
17/12/2002	Pharmacokinetics				
17/12/2002	Pharmacokinetics				

Additional Information:

An autopsy has been performed. relevant history - the patient had put on weight.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156565

Seq: 1

Gender: F

Reported: 21/08/2000

Weight: 0.00

Hospitalisation:

Age: 38

Onset Date: 20/07/2000

DOB: 26/09/1961

Outcome: Death

Causality: Causality possible

Reaction Detail

Medicine Details:

NITRAZEPAM (Suspected)		Reason:	
Batch:	0.0	Started:	Stopped:
PREDNISONE (Suspected)		Reason:	
Batch:	0.0	Started:	Stopped:
KAPANOL (Suspected)		Reason:	
Batch:	0.0	Started:	Stopped:
CLOZARIL (Suspected)		Reason:	
Batch:	575.0 Milligram	Daily	Oral
Batch:	Started: 08/04/1998	Stopped:	20/07/2000

Laboratory Investigations:

Additional Information:

An autopsy has been performed. relevant history - the patient had put on wieght.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156657 **Seq:** 1 **Gender:** F
Reported: 18/08/2000 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 14/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Zoloft ceased

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	0.0 Milligram	1 time	Oral
Batch:	Started: 31/07/2000	Stopped:	14/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156670

Seq: 1

Gender: F

Reported: 21/08/2000

Weight: 51.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 31/08/1965

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Marked agitation.	
Affect lability		Uncontrollable crying.	
Aggression			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 19/04/2000
	Stopped: 20/04/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156761 **Seq:** 1 **Gender:** F
Reported: 25/08/2000 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 01/05/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia Confusional state Hallucination Hyperreflexia Hypertonia Hypotension Pyrexia	Severe	Dystonia in lower limbs. Severe confusion	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 01/03/2000	Stopped: 30/04/2000	
TRAMADOL HYDROCHLORIDE (Suspected)		Reason:	
Capsule	400.0 Milligram	Daily	Oral
Batch:	Started: 24/04/2000	Stopped: 30/04/2000	
PERICYAZINE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FLUDROCORTISONE (Suspected)		Reason:	
	50.0 Microgram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has persisting disability due to contractures in her legs and feet. Australian prescriber vol. 25 no.1, 2002. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 156761 **Seq:** 1 **Gender:** F
Reported: 25/08/2000 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 01/05/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Treated with baclofen, cyproheptadine, botulium toxin and benserazide/levodopa also required a blood transfusion post op and spasticity required surgical tendon release x 2.
Tremor			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 01/03/2000	Stopped: 30/04/2000	
TRAMADOL HYDROCHLORIDE (Suspected)		Reason:	
Capsule	400.0 Milligram	Daily	Oral
Batch:	Started: 24/04/2000	Stopped: 30/04/2000	
PERICYAZINE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FLUDROCORTISONE (Suspected)		Reason:	
	50.0 Microgram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Patient has persisting disability due to contractures in her legs and feet. Australian prescriber vol. 25 no.1, 2002. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157138

Seq: 1

Gender: M

Reported: 29/08/2000

Weight: 76.00

Hospitalisation:

Age: 47

Onset Date: 27/07/2000

DOB: 27/07/1953

Outcome: Recovered

Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		2-3 minutes after taking zolof 100mg.	Date of recovery 27.7.00. required a visit to doctor.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking restavit. patient was on 50mg daily then he increased it himself to 100mg daily on the 26.7.00. previous known epileptic on no anti-epileptics. (had used tergetol).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157217 **Seq:** 1 **Gender:** F
Reported: 30/08/2000 **Weight:**
Hospitalisation: **Age:** 23
Onset Date: 24/08/2000 **DOB:** 08/03/1977
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise			
Nausea			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 23/08/2000 Stopped: 23/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking diane 35. reaction to stemetil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157261

Seq: 1

Gender: U

Reported: 01/09/2000

Weight:

Hospitalisation:

Age:

Onset Date: 25/08/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oculogyration			

Medicine Details:

ZOLOFT (Suspected)				Reason:	Anxiety neurosis
Tablet	50.0	Milligram	Daily		Oral
Batch:	Started:	24/08/2000	Stopped:	25/08/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157355

Seq: 1

Gender: F

Reported: 04/09/2000

Weight: 72.00

Hospitalisation:

Age: 51Y

Onset Date: 23/08/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise		Generally very unwell.	
Depersonalisation		Unreal feeling, body floating in air.	Withdrawal of zoloft.
Agitation			

Medicine Details:

ZOLOFT (Suspected)		Reason: Anxiety neurosis	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 21/08/2000	Stopped: 26/08/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking provera and amoxycillin.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157502 **Seq:** 1 **Gender:** M
Reported: 06/09/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 67
Onset Date: 18/08/2000 **DOB:** 22/10/1932
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Hyponatraemia Inappropriate antidiuretic hormone Nausea			Patient hospitalised. date of recovery 24/08/00. zolofit ceased. fluid restrict ed.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Sodium 114 osmolality c/w siadh.

Additional Information:

Patient also taking ventolin, atrovent, serevent, becloforte, coloxyl with senna. other potential precipitants for siadh in this patient include metastatic prostate cancer.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157547 **Seq:** 1 **Gender:** M
Reported: 11/09/2000 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: 08/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft ceased. given demeclocycline 150mg qid 3.7.00. date of recovery 14.8.00

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 03/08/2000 Stopped: 09/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		31/07/2000	131	
	Sodium		08/08/2000	119	
	Sodium		14/08/2000	131	

Additional Information:

Patient also taking mycostatin, coloxyl & senna, ventolin, ipratrin and solone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157726

Seq: 1

Gender: M

Reported: 13/09/2000

Weight:

Hospitalisation:

Age: 50

Onset Date: 31/12/1996

DOB: 27/11/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Movement disorder.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Anxiety neurosis
150.0 Milligram	Daily
Batch:	Started: 01/09/1996
	Stopped: 24/12/1996

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157782 **Seq:** 1 **Gender:** M
Reported: 13/09/2000 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: 12/08/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase in Chills Confusional state Nervousness Neuroleptic malignant syndrome			Olanzapine and sertraline

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started: 05/06/2000	Stopped: 12/08/2000	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Oral application	25.0 Milligram	Daily	Oral
Batch:	Started: 28/07/2000	Stopped: 14/08/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Creatine				Ck 1100
	Serum drug level				Lithium levels 12/08/00 0.8 (0.5 - 1.0).

Additional Information:

Patient also taking lithium, diazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157829

Seq: 1

Gender: M

Reported: 15/09/2000

Weight: 80.00

Hospitalisation:

Age: 38Y

Onset Date: 10/07/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Aggressive mood.	
Depersonalisation		Derealization odd somatic feeling.	
Nightmare			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram
	Daily
	Oral
Batch:	Started: 03/07/2000
	Stopped: 16/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 18/7/00.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 157945 **Seq:** 1 **Gender:** F
Reported: 20/09/2000 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 59Y
Onset Date: 14/07/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety Arrhythmia Confusional state Diarrhoea Palpitations Serotonin syndrome			Observation and tx in hospital.

Medicine Details:

ZOLOFT (Interaction)		Reason:	
50.0 Milligram		Daily	
Batch:	Started:	Stopped:	
HYPERICUM-ST JOHN'S WORT (Interaction)		Reason: Anxiety neurosis	
2.0 Dose Unspecified		Daily	
Batch:	Started: 22/06/2000	Stopped: 14/07/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking isoptin, menorest, gastrostop, zinc chelate. long history of wolff-parkinsons white syndrome.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158103 **Seq:** 1 **Gender:** F
Reported: 27/09/2000 **Weight:**
Hospitalisation: **Age:** 56
Onset Date: 01/09/2000 **DOB:** 07/02/1944
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia Diarrhoea Pruritus Rash follicular			Required a visit to doctor

Medicine Details:

OESTRADIOL IMPLANT (Suspected)	Reason:	Menopausal symptoms
Batch:	Started:	Stopped:
	0.0	CONTIN
ZOLOFT (Suspected)	Reason:	
Batch:	Started:	Stopped:
	50.0 Milligram Daily	28/09/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced migraine with oestrogen. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158143 Seq: 1

Gender: M

Reported: 28/09/2000

Weight: 70.00

Hospitalisation:

Age: 34

Onset Date: 12/09/2000

DOB: 25/03/1966

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Sensation of heat in hands and forearms.	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected)				Reason:	Depression
Tablet	100.0	Milligram	Daily		Oral
Batch:	Started:	11/09/2000	Stopped:	14/09/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158312

Seq: 1

Gender: F

Reported: 09/10/2000

Weight: 49.00

Hospitalisation:

Age: 54

Onset Date: 03/09/2000

DOB: 02/01/1946

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Date of recovery 30.9.00.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 04/08/2000
	Stopped: 15/09/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158316

Seq: 1

Gender: F

Reported: 09/10/2000

Weight: 60.00

Hospitalisation:

Age: 28Y

Onset Date: 16/08/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response unexpected		Coldsores on mouth - none since commencing zoloft.	
Menorrhagia		Next 2 menstrual periods extremely heavy.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram
	Daily
	Oral
Batch:	Started: 10/07/2000
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking monofeme.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158448 **Seq:** 1 **Gender:** M
Reported: 09/10/2000 **Weight:**
Hospitalisation: **Age:** 73
Onset Date: 11/07/2000 **DOB:** 08/12/1926
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Headache Nausea		Shaking hands.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression
	50.0 Milligram	1 time
Batch:	Started: 11/07/2000	Stopped: 11/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking gliclazide, perindopril, omeprazole, pravastatin, metformin and paracetamol. patient has no known allergies. history of anaemia and niddm.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158685 **Seq:** 1 **Gender:** F
Reported: 20/10/2000 **Weight:** 45.00
Hospitalisation: **Age:** 82Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastritis Weight decreased Dysphagia Oesophageal stenosis		Antral gastritis Weight loss from 50kg to 45kg.	

Medicine Details:

CELEBREX (Suspected)		Reason:	
Capsule	0.0	Oral	
Batch:	Started:	Stopped:	CONTIN
ROCALTROL (Suspected)		Reason:	
Capsule	0.0	Oral	
Batch:	Started:	Stopped:	CONTIN
ZOLOFT (Suspected)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	CONTIN
FOSAMAX (Suspected)		Reason: Osteoporosis	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/01/1998	Stopped:	28/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Radiology				Endoscopy - a barium meal swallow showed a long narrow stricture of the proximal esophagus. antral gastritis tested negative for helicobacter pylori

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158734

Seq: 1

Gender: F

Reported: 23/10/2000

Weight:

Hospitalisation:

Age: 09Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Faecal incontinence			
Urinary incontinence			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158735

Seq: 1

Gender: M

Reported: 23/10/2000

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Severe	Severe bowel problems for 3 months.	Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158741

Seq: 1

Gender: F

Reported: 23/10/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance Migraine		Visual disturbance and then a headache.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158744

Seq: 1

Gender: F

Reported: 23/10/2000

Weight: 50.00

Hospitalisation:

Age: 39

Onset Date: 31/01/2000

DOB: 24/04/1960

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Chronic dry cough.	Zolof ceased. required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected)	Reason: Anxiety neurosis
50.0 Milligram	Daily
Batch:	Started: 16/11/1999
	Stopped: 06/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - dermestril, rhinocort nasal, atrovent nasal, ranitidine and prepulsid. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158767 **Seq:** 1 **Gender:** F
Reported: 23/10/2000 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: 03/10/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Temporal lobe epileptic fit.	Zoloft reduced to 100mg. sodium valproate given.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No history of convulsions.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158769

Seq: 1

Gender: M

Reported: 23/10/2000

Weight:

Hospitalisation:

Age: 30Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium Paranoia Psychotic disorder			Zoloft ceased. antipsychotic

Medicine Details:

ZOLOFT (Suspected)	Reason:
Tablet	400.0 Milligram
Batch:	Daily
	Oral
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158809

Seq: 1

Gender: U

Reported: 23/10/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia		Feeling of weakness in her legs.	
Hypoaesthesia		Numbness in her fingers and toes in last 18	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 158839

Seq: 1

Gender: F

Reported: 26/10/2000

Weight: 59.00

Hospitalisation:

Age: 72

Onset Date:

DOB: 23/08/1928

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Zoloft ceased

Medicine Details:

LAMICTAL (Interaction)	reason: Other&unspecified epilepsy
400.0 Milligram	Daily
Batch:	started: 20/09/1997
stopped:	
ZOLOFT (Interaction)	reason: Depression
50.0 Milligram	Daily
Batch:	started: 14/04/2000
stopped: 28/06/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking zoton, serepax. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159019

Seq: 1

Gender: F

Reported: 02/11/2000

Weight: 68.00

Hospitalisation:

Age: 49Y

Onset Date: 26/10/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Severe	Giddiness, a sense of inbalance.	Date of recovery 27/10/2000.
Agitation		Severe agitation.	
Hyperhidrosis			
Vomiting			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
25.0 Milligram	Daily
Batch:	Started: 23/10/2000
	Stopped: 26/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - doxyhexal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159087 **Seq:** 1 **Gender:** M
Reported: 06/11/2000 **Weight:**
Hospitalisation: **Age:** 39
Onset Date: 30/10/2000 **DOB:** 19/10/1961
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal Drug ineffective Speech disorder Agitation Headache		Mind racing No change in depression. Talking rapidly Unsettled jittery	Diazepam 5mg. advised to cease zoloft.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 23/10/2000 Stopped: 31/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on zoloft 25mg for 4 days then 50mg for 3 days. patient was also taking avapro, lipex.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159123 **Seq:** 1 **Gender:** M
Reported: 06/11/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 28Y
Onset Date: 16/05/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Patient was transferred to

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 16/05/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159126

Seq: 1

Gender: F

Reported: 07/11/2000

Weight: 95.00

Hospitalisation:

Age: 32Y

Onset Date: 31/05/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Unusual visual disturbance.	
Drug withdrawal syndrome			
Fatigue			
Nystagmus			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 01/11/1999
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking tritace, natrilix, panadeine forte. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159255

Seq: 1

Gender: F

Reported: 13/11/2000

Weight:

Hospitalisation:

Age: AD

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities		Child was born with a deformity (type	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient taking 100mg zoloft once daily prior to and during pregnancy, reduced zoloft to 50mg once daily in last trimester. child born with an unknown deformity.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159357 **Seq:** 1 **Gender:** F
Reported: 16/11/2000 **Weight:**
Hospitalisation: **Age:** 72Y
Onset Date: 07/07/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started: 30/05/2000	Stopped:	
WARFARIN SODIUM (Interaction)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	
SERTRALINE HYDROCHLORIDE (Interaction)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started: 06/07/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International		26/05/2000	3.2	Increased inr.
	International		03/07/2000	2.4	Increased inr.
	International		07/07/2000	3.3	Increased inr.
	International		10/07/2000	2.4	Increased inr.

Additional Information:

Patient also taking risperidone, coloxyl with senna and trandolapril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159468

Seq: 1

Gender: F

Reported: 21/11/2000

Weight: 68.00

Hospitalisation:

Age: 32Y

Onset Date: 29/10/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			Date of recovery 16/11/2000. skin completely settled over the next 10 days.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
25.0 Milligram	Daily
Batch:	Started: 20/10/2000
	Stopped: 30/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft therapy was taken at 25mg/daily then increased to 50mg/daily. patient also taking - ferrograd c.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159522 **Seq:** 1 **Gender:** F
Reported: 24/11/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 20Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

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

Medicine Details:

ZOLOFT (Suspected)	Reason:		
	25.0 Milligram	Total	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159535

Seq: 1

Gender: M

Reported: 24/11/2000

Weight:

Hospitalisation:

Age: 37Y

Onset Date: 23/10/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Agitation Constipation Dry mouth Hallucination Hypertonia		Shaking	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 20/10/2000
	Stopped: 23/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159578

Seq: 1

Gender: M

Reported: 29/11/2000

Weight: 72.00

Hospitalisation:

Age: 37Y

Onset Date: 22/10/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance Hypertonia Agitation Constipation Dry mouth Hallucination		Saw stationary objects move. Tighting of muscles in arms.	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 20/10/2000	Stopped: 23/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159760

Seq: 1

Gender: F

Reported: 05/12/2000

Weight: 80.00

Hospitalisation:

Age: 32

Onset Date: 18/11/2000

DOB: 16/06/1968

Outcome: Unknown

Causality: Causality possible

Reaction Detail

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

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 01/06/2000
	Stopped: 28/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159808 **Seq:** 1 **Gender:** F
Reported: 08/12/2000 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neurosis		Kicking legs about in the air.	Valium to sedate the patient.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159811 **Seq:** 1 **Gender:** F
Reported: 08/12/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haemorrhage Purpura		Bleeding	Zoloft was ceased and recommenced 5 months later.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pateint experienced symptoms after 3 months of therapy with zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159823

Seq: 1

Gender: F

Reported: 11/12/2000

Weight: 44.00

Hospitalisation:

Age: 13

Onset Date: 30/11/2000

DOB: 28/10/1987

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome Headache Nausea			Required a visit to doctor.

Medicine Details:

CELEBREX (Suspected)		Reason: Pain
Capsule	200.0 Milligram	Daily Oral
Batch:	Started: 01/09/2000	Stopped: 29/11/2000
ZOLOFT (Suspected)		Reason: Depression
	50.0 Milligram	Daily
Batch:	Started: 24/11/2000	Stopped: 04/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159836 **Seq:** 1 **Gender:** F
Reported: 11/12/2000 **Weight:**
Hospitalisation: **Age:** 80
Onset Date: 19/10/2000 **DOB:** 04/11/1919
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure-type episode several hrs after first	None - ceased zoloft.

Medicine Details:

FELODIPINE (Other drug)	reason:	Essential benign hypertension
Batch:	Started:	Stopped:
0.0		
FERRO-GRADUMET (Other drug)	reason:	
Batch:	Started:	Stopped:
0.0		
ZOLOFT (Suspected)	reason:	Depression
Batch:	Started:	Stopped:
1.0 Dose Unspecified 1 time	19/10/2000	19/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous seizure-type episodes. no known drug allergies. patient has alzheimer's disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159851 **Seq:** 1 **Gender:** F
Reported: 11/12/2000 **Weight:**
Hospitalisation: **Age:** 59Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation	Severe	Severe agitation	
Insomnia	Severe	Severe insomnia	

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 17/05/2000	Stopped:	27/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

After taking zoloft for 10 days patient experienced severe symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159903 **Seq:** 1 **Gender:** F
Reported: 11/12/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 52Y
Onset Date: 19/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation		Atrial flutter when she "turns" in bed.	Patient admitted to emergency department.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 14/04/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159925 **Seq:** 1 **Gender:** M
Reported: 11/12/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 72
Onset Date: 30/10/2000 **DOB:** 10/06/1928
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Dizziness			Patient was hospitalised.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 01/09/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: sustained a fracture of the left neck of femur from a fall. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159960

Seq: 1

Gender: M

Reported: 13/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia Urinary retention			Patient was presented at hospital with urinary retention.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - amiodorine. relevant history - atrial fibrillation and prostatism.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159965 **Seq:** 1 **Gender:** F
Reported: 13/12/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 22/05/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 18/05/2000	Stopped: 22/05/2000	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159966

Seq: 1

Gender: F

Reported: 13/12/2000

Weight:

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Nocturnal enuresis.	

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1999	Stopped: 28/02/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous history of fh enuresis. symptoms occurred after the original dose of 100mg was increased to 200mg. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159970

Seq: 1

Gender: M

Reported: 14/12/2000

Weight:

Hospitalisation:

Age: 45Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Bruxism Drug ineffective Ejaculation failure		Nausea when he yawns.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159971 **Seq:** 1 **Gender:** F
Reported: 14/12/2000 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Disturbance in attention			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159974

Seq: 1

Gender: F

Reported: 14/12/2000

Weight: 59.00

Hospitalisation:

Age: 44

Onset Date:

DOB: 18/04/1956

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Persistent watery diarrhoea	Zoloft ceased

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: 19/09/2000
	Stopped: 02/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking depo-provera, polaramine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 159993 **Seq:** 1 **Gender:** F
Reported: 08/12/2000 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotonia neonatal		Baby born "floppy".	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Whilst pregnant, a female patient was taking zoloft. the baby was born "floppy" which resolved over the next several days without any adverse events.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160037

Seq: 1

Gender: F

Reported: 14/12/2000

Weight: 73.00

Hospitalisation:

Age: 39Y

Onset Date: 05/12/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysphagia		Swallowing movements when asleep on reduced dose.	

Medicine Details:

ZOLOFT (Suspected)				Reason:	Depression
Tablet	100.0	Milligram	Daily		Oral
Batch:	Started:	01/06/1999	Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred when dose of zoloft was reduced from 100mg to 50mg. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160054 **Seq:** 1 **Gender:** F
Reported: 14/12/2000 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 27/04/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pyrexia Confusional state Convulsion Hyperreflexia Hypertonia		High temperature	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 27/04/2000	Stopped:	01/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking tramodol, neulactil, florinef.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160102 **Seq:** 1 **Gender:** F
Reported: 14/12/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 90Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Patient was admitted to hospitalised. zoloft was stopped
Serotonin syndrome			
Tremor			

Medicine Details:

HYPERICUM-ST JOHN'S WORT (Interaction)		Reason:	
Tablet	0.0		Oral
Batch:	Started:		Stopped:
ZOLOFT (Interaction)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking celebrex, panadol, valium.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160115 **Seq:** 1 **Gender:** F
Reported: 20/12/2000 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 06/12/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Cessation of zoloft and fluid restriction. patient was

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Sodium decreased to 114, had been 128 prior to commencing zoloft, returned to 128 with cessation of zoloft and fluid restriction

Additional Information:

Patient was also taking tritace, astrix, pravachol.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160150

Seq: 1

Gender: M

Reported: 21/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Visual disturbance		Dimmed vision.	
Hypertonia		Felt stiff.	
Paraesthesia		Tingling sensation in arms.	
Dry mouth			
Dyspnoea			
Fatigue			
Palpitations			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160152

Seq: 1

Gender: M

Reported: 21/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alcohol intolerance			
Drug level increased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient reports that his blood alcohol level was above the legal limit. he claims to have only consumed light beer, insufficient to produce the measured blood alcohol reading.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160153

Seq: 1

Gender: M

Reported: 21/12/2000

Weight:

Hospitalisation:

Age: 65Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		After 2d blood sugar level significantly	Doctor discontinued the zolof and patient returned to normal.
Diabetes mellitus			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160154 **Seq:** 1 **Gender:** M
Reported: 21/12/2000 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 05/05/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epistaxis		Could last up to 30 minutes.	

Medicine Details:

ZOLOFT (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 01/05/2000 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.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160162 **Seq:** 1 **Gender:** F
Reported: 21/12/2000 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Infertility female			

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	3Y

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced zolofit when she was 17 and continued through till she was 20 she is now 23 almost 24 and is unable to get pregnant.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160169

Seq: 1

Gender: F

Reported: 21/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			Diazepam helped reduce side effects within 15 min of dosing.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160170

Seq: 1

Gender: F

Reported: 21/12/2000

Weight:

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Purpura			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160171

Seq: 1

Gender: F

Reported: 21/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aphthous stomatitis		Ulcers on the tip of tongue	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking aspirin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160172

Seq: 1

Gender: F

Reported: 21/12/2000

Weight:

Hospitalisation:

Age: 30Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Pins and needles in finger tips.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160173 **Seq:** 1 **Gender:** F
Reported: 21/12/2000 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			Zoloft was ceased and patient improved within 24 hrs.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160174

Seq: 1

Gender: F

Reported: 21/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain within 9-10 months of use.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160207 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:** 41Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching Palpitations		"little fits in the brain".	Condition is managed with inaleral and rivotril. zoloft discontinued

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Neurologist diagnosed tourette's-like condition induced by zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160208

Seq: 1

Gender: M

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 44Y

Onset Date: 09/05/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Muscle twitching and jerking whilst asleep.	
Insomnia			
Libido decreased			

Medicine Details:

TEMAZEPAM (Suspected)		Reason:	
Oral application	0.0		Oral
Batch:	Started:		Stopped:
ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zoloft was increased to 100mg 6 weeks ago.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160209 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: 29/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonus of lower jaw lasting several	Date of recovery: 31/5/2000.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 29/05/2000	Stopped:	30/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred after first dose. doctor suggested repeat dose following day with same result.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160211

Seq: 1

Gender: M

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 73Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hallucination			
Tremor			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160212 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Decrease in mood and teariness.	

Medicine Details:

ZOLOFT (Interaction)		Reason:	
Tablet	0.0		Oral
Batch:	Started:		Stopped:
FLAGYL (Interaction)		Reason:	
Tablet	0.0		Oral
Batch:	Started:	S TERM	Stopped:
AMOXICILLIN TRIHYDRATE (Interaction)		Reason:	
Oral application	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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160213

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 64Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue		Increasing exhaustion.	
Hypertension			
Hyponatraemia			Zoloft decreased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160215

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 58Y

Onset Date: 01/07/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glaucoma		Early glaucoma.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160216 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:** 67Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Nausea			
Serotonin syndrome			
Tremor			

Medicine Details:

CALTRATE (Other drug)	Reason:
Tablet	0.0
Batch:	Started:
	Stopped:
FOLIC ACID (Other drug)	Reason:
Tablet	0.0
Batch:	Started:
	Stopped:
STEMETIL (Other drug)	Reason:
Tablet	0.0
Batch:	Started:
	Stopped:
PREMARIN (Other drug)	Reason:
Tablet	0.0
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been taking zoloft 50mg which was later increased to 100mg. two to three weeks later the patient was commenced on celebrex.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160216

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 67Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)				Reason:	
Tablet	50.0	Milligram	Daily	Oral	
Batch:	Started:	Stopped:			
CELEBREX (Suspected)				Reason: Osteoarthritis	
Capsule	200.0	Milligram	Daily	Oral	
Batch:	Started:	Stopped:			

Laboratory Investigations:

Additional Information:

Patient had been taking zoloft 50mg which was later increased to 100mg. two to three weeks later the patient was commenced on celebrex.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160232

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Night sweats	
Weight decreased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160233

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160234

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking oral contraceptive.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160236 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea			
Weight increased			

Medicine Details:

ZOLOFT (Suspected)	Reason:
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 01/09/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160238

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased			Zoloft stopped

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160239

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160240

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age:

Onset Date: 31/05/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			Zoloft ceased

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160241

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age:

Onset Date: 31/05/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			
Anxiety			
Confusional state			
Drug withdrawal syndrome			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160243 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: 18/05/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Abnormal dreams Diarrhoea Hot flush Nausea Tremor			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Although post-menopausal, patient had not previously experienced hot flushes and that these have only occurred after taking zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160245 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 28/05/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Severe	Severe headache	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 28/05/2000	Stopped:	30/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160247

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 20Y

Onset Date: 29/05/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Vomiting			

Medicine Details:

ZOLOFT (Suspected)	Reason:		
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 28/05/2000	Stopped: 29/05/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160248 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: 29/05/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Itchy rash on abdomen, legs, back	

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 20/05/2000	Stopped:	29/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A patient started on zoloft 50mg for 7 days, then onto 100mg/day. patient also taking hrt drug therapy (unspecified).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160250

Seq: 1

Gender: M

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 44Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason:		
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	5D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160253

Seq: 1

Gender: M

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 48Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased			

Medicine Details:

ASIG (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason:
Tablet 100.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160257 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:** 38Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia			Zoloft ceased. therapy changed to arapax.
Tinnitus			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160259

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 37Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Severe and persistent diarrhoea	Zoloft ceased, serzone started.
Anxiety			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on various doses of zoloft 25mg then increased to 50mg, 75mg, 100mg and 200mg. dose reduced to 100mg but diarrhoea persisted. zoloft ceased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160260

Seq: 1

Gender: M

Reported: 22/12/2000

Weight:

Hospitalisation:

Age: 51Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Arthralgia		Sore hips, knees, base of skull	
Myalgia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160264

Seq: 1

Gender: F

Reported: 22/12/2000

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hair texture abnormal		Hair would not hold a perm	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160265 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Elevation in prolactin levels.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160267 **Seq:** 1 **Gender:** F
Reported: 22/12/2000 **Weight:**
Hospitalisation: **Age:** 31Y
Onset Date: 01/09/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hot flush			

Medicine Details:

DEPO-PROVERA (Suspected)		Reason:	
Oral application	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on zolof 25mg increased to 50mg. p/h of hormone imbalance.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160321

Seq: 1

Gender: M

Reported: 20/12/2000

Weight: 58.00

Hospitalisation:

Age: 37

Onset Date:

DOB: 05/08/1963

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Therapeutic response unexpecte		Genital herpes - no problems since starting	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Genital herpes - no problems since starting sertraline - almost constant befor e.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160332

Seq: 1

Gender: M

Reported: 22/12/2000

Weight: 0.00

Hospitalisation:

Age: 25Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast mass		Breast lump, biopsied but no result	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160398 **Seq:** 1 **Gender:** F
Reported: 04/01/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Dry tickling cough, 3-4 bursts of coughing	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking enalapril, nifedipine, medroxyprogesterone - oestrogens conjugated. patient has been on other medications for at least a few years. developed a progressively worsening cough over last 4 months since starting zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160399

Seq: 1

Gender: F

Reported: 04/01/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			
Diarrhoea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient who experienced loose stools and increased anxiety when her dose of zoloft was increased from 25mg to 50mg daily. she had been taking zoloft for a period of 4 years and had tapered the dosage to 25mg daily but had been instructed by her doctor to increase the dose to 50mg daily again. she had no problems previously when taking zoloft 50mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160418 **Seq:** 1 **Gender:** F
Reported: 05/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 17Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state		Became confused and disoriented.	
Serotonin syndrome			Patient was hospitalised.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had a history of sensitivity to other medications including maxolon.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160422 **Seq:** 1 **Gender:** F
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Severe	Severe headaches.	
Hypertension			

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	6.2 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is an extremely drug sensitive individual.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160424 **Seq:** 1 **Gender:** M
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Became psychotic or manic.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was referred to a psychiatrist.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160427 **Seq:** 1 **Gender:** M
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:** 10Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Hive like rash.	Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160428 **Seq:** 1 **Gender:** F
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:** 75Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Loose stools.	
Nausea		Sick in the stomach.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose was reduced to 25mg which she took for 3 days and has now experienced loose stools.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160430 **Seq:** 1 **Gender:** F
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:** 27Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache			
Vomiting			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160431 **Seq:** 1 **Gender:** F
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			
Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160432

Seq: 1

Gender: M

Reported: 05/01/2001

Weight:

Hospitalisation:

Age: 49Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy, irritated scalp.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160433

Seq: 1

Gender: M

Reported: 05/01/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gastrooesophageal reflux diseases		Causes him to vomit.	

Medicine Details:

ZOLOFT (Suspected)	Reason:		
Tablet	200.0 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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160435 **Seq:** 1 **Gender:** F
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Conjunctivitis		Itchy eyes.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160436 **Seq:** 1 **Gender:** F
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			Treated with zantac. zoloft is continuing.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160437

Seq: 1

Gender: F

Reported: 05/01/2001

Weight:

Hospitalisation:

Age: 35Y

Onset Date: 15/07/2000

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin discolouration		Skin started to turn yellow, 3 hrs after	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2000	Stopped:	17/07/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prednisone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160439 **Seq:** 1 **Gender:** F
Reported: 05/01/2001 **Weight:**
Hospitalisation: **Age:** 26Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			
Anxiety			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160440

Seq: 1

Gender: F

Reported: 05/01/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160454 **Seq:** 1 **Gender:** F
Reported: 08/01/2001 **Weight:** 70.00
Hospitalisation: **Age:** 63
Onset Date: **DOB:** 01/09/1937
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Malaise		Felt terrible	
Amnesia		Impaired short term memory	
Headache		Right sided headache	
Paraesthesia		Tingling right side of face	Zoloft ceased

Medicine Details:

OROXINE (Other drug)	Reason: Myxedema
50.0 Microgram Daily	
Batch:	Started: 01/01/1998 Stopped:
ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 11/10/2000 Stopped: 06/12/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous tia, benign essential tremor. full resolution on cessation of zoloft. the dosage start date is not accurate but indicates that start occurred sometime during the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160470 **Seq:** 1 **Gender:** M
Reported: 09/01/2001 **Weight:**
Hospitalisation: **Age:** 73Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Became rigid	
Gait disturbance		Unstable gait	
Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking adalat, ginger (herb preparation). patient was started on 50mg zoloft, the dose was reduced to 25mg because of nausea, the patient then developed other symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160471

Seq: 1

Gender: F

Reported: 09/01/2001

Weight:

Hospitalisation:

Age: 45Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient on zoloft for 3 weeks showed elevated lft's.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160473

Seq: 1

Gender: M

Reported: 09/01/2001

Weight:

Hospitalisation:

Age: 70Y

Onset Date: 14/11/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			

Medicine Details:

MORPHINE SULPHATE (Suspected)		Reason:	
Injection	0.0	Intravenous	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160474

Seq: 1

Gender: M

Reported: 09/01/2001

Weight:

Hospitalisation:

Age: 36Y

Onset Date: 01/12/1999

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			
Libido decreased			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160475 **Seq:** 1 **Gender:** F
Reported: 09/01/2001 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: 16/01/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Diarrhoea Vomiting			Given klacid and panamax.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 14/01/2000	Stopped:	20/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking nordiol, flixotide, propionate, ventolin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160476 **Seq:** 1 **Gender:** F
Reported: 09/01/2001 **Weight:**
Hospitalisation: **Age:** 22Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dehydration			Given iv fluids, ceased klacid, panamax, then taken off zoloft.
Syncope			

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 14/01/2000	Stopped:	20/01/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

See seq 01 for other drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160489

Seq: 1

Gender: M

Reported: 09/01/2001

Weight:

Hospitalisation:

Age: 45Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160490 **Seq:** 1 **Gender:** F
Reported: 09/01/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness		Feeling as though she were about to "pass	

Medicine Details:

BREVINOR-1 (Other drug)		Reason:	
Tablet	0.0		Oral
Batch:	Started:		Stopped:
ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160492

Seq: 1

Gender: M

Reported: 09/01/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction worsened when the dose was increased to 150mg daily. patient reported similar experience with previous therapy with efexor (venlafaxine), luvox (fluvoxamine) and cipramil (citalopram).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160495 **Seq:** 1 **Gender:** M
Reported: 09/01/2001 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160496 **Seq:** 1 **Gender:** M
Reported: 09/01/2001 **Weight:**
Hospitalisation: **Age:** 11Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Bed wetting increased to every night.	
Epistaxis			Dose reduced back to 50mg.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/09/1999	Stopped:	28/11/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions occurred when dose was increased to 100mg. patient has a history of nosebleeding and also bed wetting. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160497

Seq: 1

Gender: F

Reported: 09/01/2001

Weight:

Hospitalisation:

Age: 70Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness			
Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160498

Seq: 1

Gender: M

Reported: 09/01/2001

Weight:

Hospitalisation:

Age: 55Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Erection difficulties.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160499

Seq: 1

Gender: M

Reported: 09/01/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Insomnia			Dose was reduced to 50mg.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160590 **Seq:** 1 **Gender:** F
Reported: 12/01/2001 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: 01/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia		Patient experienced memory problems.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prescribed zoloft in hope that it would have an appetite suppressant effect as the patient was on a low fat weight loss diet.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160592 **Seq:** 1 **Gender:** F
Reported: 12/01/2001 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Nausea for the first 2 weeks.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160597 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tachycardia			Zoloft ceased and switched to cipramil.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160599 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 74Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Severe	Severe diarrhoea (4-8 times a day).	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient stopped taking zoloft and the depressive symptoms re-emerged, so zoloft was again initiated with the same result of severe diarrhoea.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160600

Seq: 1

Gender: M

Reported: 15/01/2001

Weight:

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient switched onto an alternate ssri.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160601 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 23Y
Onset Date: 15/07/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea		Patient developed constant nausea.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160603 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anorgasmia		Continual anorgasmia.	Increased the dose to 200mg, her depression is lifting but the anorgasmia is still a problem.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160605

Seq: 1

Gender: M

Reported: 15/01/2001

Weight:

Hospitalisation:

Age: 45Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160606 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Severe	Severe nausea.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160607 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 64Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Fatigue		Progressive fatigue over the past 2 months	

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 16/09/1997	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking becloforte, serevent, valium and serepax.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160641 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Psychotic disorder		Threatened her husband with a knife.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160649 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 64Y
Onset Date: 22/07/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Depersonalisation Agitation Anxiety Pneumonia		Developed profound hyponatraemia. Feeling of being "spaced out".	Patient was given serepax, then admitted to hospital.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking serepax and seprtin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160651 **Seq:** 1 **Gender:** M
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 34Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	0.0		Oral
Batch:	Started:	Stopped:	
PANADEINE FORTE (Suspected)		Reason:	
Tablet	0.0		Oral
Batch:	Started:	Stopped:	
TEMAZEPAM (Suspected)		Reason:	
Capsule	0.0		Oral
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient taking zoloft overdosed on a combination of drugs (unsure of quantity)



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160653 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 58Y
Onset Date: 29/06/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epistaxis		An episode of nosebleeding.	
Uterine haemorrhage		Vaginal bleeding lasting for approximately	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Later patient had vaginal bleeding, lasting for 3 weeks resulting in a curette in august.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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Report Detail

Case Number: 160654 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 25Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced a fit.	

Medicine Details:

EPILIM (Interaction)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Interaction)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160655 **Seq:** 1 **Gender:** F
Reported: 15/01/2001 **Weight:**
Hospitalisation: **Age:** 88Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160674 **Seq:** 1 **Gender:** F
Reported: 17/01/2001 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anxiety			

Medicine Details:

CAFFEINE (Suspected)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160678 **Seq:** 1 **Gender:** F
Reported: 17/01/2001 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flatulence		Abdominal distention	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160679

Seq: 1

Gender: F

Reported: 17/01/2001

Weight:

Hospitalisation:

Age: 30Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache	Severe	Severe headache	
Agitation			Zoloft ceased.
Nausea			
Vomiting			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160680

Seq: 1

Gender: F

Reported: 17/01/2001

Weight:

Hospitalisation:

Age: 35Y

Onset Date: 05/06/2000

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Pimple like rash	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason:		
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 29/05/2000	Stopped: 05/06/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160687

Seq: 1

Gender: F

Reported: 09/01/2000

Weight:

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Elevated serum levels of clozaril	

Medicine Details:

CLOZARIL (Interaction)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Interaction)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160742

Seq: 1

Gender: M

Reported: 17/01/2001

Weight: 0.00

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thyroid function test abnormal		Thyroid dysfunction/increase in thyroid	
Thyroid disorder			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160743 **Seq:** 1 **Gender:** U
Reported: 17/01/2001 **Weight:**
Hospitalisation: **Age:** 70Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160744 **Seq:** 1 **Gender:** F
Reported: 17/01/2001 **Weight:**
Hospitalisation: **Age:** 42Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glaucoma			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160745

Seq: 1

Gender: F

Reported: 17/01/2001

Weight:

Hospitalisation:

Age: 30Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Peptic ulcer haemorrhage		Increasing bleeding from already	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160783 **Seq:** 1 **Gender:** F
Reported: 19/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 15/05/2000 **DOB:** 20/08/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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 Pharmacokinetics				Ct showed hepatomegaly. 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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160783 **Seq:** 1 **Gender:** F
Reported: 19/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 15/05/2000 **DOB:** 20/08/1963
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

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

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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160854 **Seq:** 1 **Gender:** M
Reported: 22/01/2001 **Weight:** 72.00
Hospitalisation: **Age:** 32Y
Onset Date: 09/01/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular Pruritus Pyrexia		Pimply looking rash lower back, shoulders,	Phenergan 25mg tds and prednisolone 50mg/day. date of recovery: 17/1/2001.

Medicine Details:

TEGRETOL (Suspected)	Reason:
400.0 Milligram Daily	
Batch:	Started: 01/11/2000 Stopped: 09/01/2001
ZOLOFT (Suspected)	Reason:
200.0 Milligram Daily	
Batch:	Started: Stopped: 09/01/2001
LARGACTIL (Suspected)	Reason:
25.0 Milligram Daily	
Batch:	Started: Stopped: 09/01/2001
ORUVAIL SR (Suspected)	Reason:
200.0 Milligram Daily	
Batch:	Started: Stopped: 09/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160854

Seq: 1

Gender: M

Reported: 22/01/2001

Weight: 72.00

Hospitalisation:

Age: 32Y

Onset Date: 09/01/2001

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ZOTON (Suspected)

Reason:

30.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160866 **Seq:** 1 **Gender:** F
Reported: 23/01/2001 **Weight:**
Hospitalisation: **Age:** 61Y
Onset Date: 08/08/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea Agitation Cardiac failure Hyperventilation		Exertional dyspnoea	

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	0.0		Oral
Batch:	Started:	Stopped:	
BETALOC (Suspected)		Reason:	
Tablet	0.0		Oral
Batch:	Started:	Stopped:	
NORVASC (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160868 **Seq:** 1 **Gender:** F
Reported: 24/01/2001 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 31/12/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression			Patient recovered 24 hrs later.

Medicine Details:

TELFAST (Interaction)	Reason:
0.0	
Batch:	Started: Stopped:
ZOLOFT (Interaction)	Reason: Depression
25.0 Milligram Daily	
Batch:	Started: 28/11/2000 Stopped:
PREMARIN (Other drug)	Reason: Menopausal symptoms
625.0 Microgram Daily	
Batch:	Started: 12/04/2000 Stopped:
OROXINE (Other drug)	Reason:
50.0 Microgram Daily	
Batch:	Started: 12/04/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Same reaction was repeated 2 weeks later for separate insect bite and treatment with telfast. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160890 **Seq:** 1 **Gender:** F
Reported: 24/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 90Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Fatigue Hyponatraemia			Patient hospitalised.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160892 **Seq:** 1 **Gender:** F
Reported: 24/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 35Y
Onset Date: 09/11/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tetany		Tetany of the lower limbs.	Patient admitted to icu.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started: 01/05/2000	Stopped:	28/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced reaction when dose of zoloft was increased from 150mg to 200mg. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160893

Seq: 1

Gender: M

Reported: 24/01/2001

Weight:

Hospitalisation:

Age: 80Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160895

Seq: 1

Gender: F

Reported: 24/01/2001

Weight:

Hospitalisation:

Age: 59Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cholangitis			
Pancreatitis			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

A patient taking zoloft was diagnosed with lymphoplasmocytic sclerosing, pancreatitis and cholangitis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160896 **Seq:** 1 **Gender:** M
Reported: 24/01/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 35Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			Patient hospitalised.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160907 **Seq:** 1 **Gender:** F
Reported: 23/01/2001 **Weight:**
Hospitalisation: **Age:** 79Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea	Severe	Severe nausea	
Anorexia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160908

Seq: 1

Gender: F

Reported: 23/01/2001

Weight:

Hospitalisation:

Age: 26Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking contraceptive pill (unspecified).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160913 **Seq:** 1 **Gender:** F
Reported: 24/01/2001 **Weight:**
Hospitalisation: **Age:** 15Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation			Dose of zoloft decreased to

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160914 **Seq:** 1 **Gender:** M
Reported: 24/01/2001 **Weight:**
Hospitalisation: **Age:** 43Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Libido decreased		Loss of sexual desire	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160915

Seq: 1

Gender: F

Reported: 24/01/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms		Muscle spasms	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160931 **Seq:** 1 **Gender:** F
Reported: 25/01/2001 **Weight:**
Hospitalisation: **Age:** 69Y
Onset Date: 27/04/2000 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Convulsion Hyperreflexia Hypertonia Pyrexia Serotonin syndrome			

Medicine Details:

NEULACTIL (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
FLORINEF (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 27/04/2000	Stopped: 01/05/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160932

Seq: 1

Gender: M

Reported: 25/01/2001

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Within the first month patient suffered 2 epileptic fits. his epileptic medication was also changed during this time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 160977

Seq: 1

Gender: F

Reported: 29/01/2001

Weight: 54.00

Hospitalisation:

Age: 19

Onset Date: 31/01/2001

DOB: 16/02/1981

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Required a visit to doctor. date of recovery 01/01. zoloft

Medicine Details:

NORIMIN (Other drug)		Reason:	
Batch:		1.0 Dose Unspecified Daily	
Started: 01/01/2000		Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet		150.0 Milligram Daily	Oral
Batch:		Started: 27/12/2000	Stopped: 02/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161004

Seq: 1

Gender: F

Reported: 25/01/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			Ceased zoloft

Medicine Details:

ZOLOFT (Suspected)	reason:
Tablet	200.0 Milligram
Batch:	Daily
	Oral
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after increase of zoloft to 200mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161007

Seq: 1

Gender: M

Reported: 25/01/2001

Weight:

Hospitalisation:

Age: 20Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161024

Seq: 1

Gender: F

Reported: 24/01/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Neonatal disorder		Baby born with cerebral palsy.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161076 **Seq:** 1 **Gender:** F
Reported: 31/01/2001 **Weight:**
Hospitalisation: **Age:** 88Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia			Dose had been reduced from 100mg to 50mg daily.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161289 **Seq:** 1 **Gender:** F
Reported: 08/02/2001 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 69
Onset Date: 21/01/2001 **DOB:** 18/12/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Severe	Severe hyponatraemia	Patient was hospitalised. 3% saline infusion.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	200.0 Milligram Daily Oral
Batch:	Started: 21/01/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking kalma, oroxine, zyprexa, temazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161415 **Seq:** 1 **Gender:** F
Reported: 12/02/2001 **Weight:**
Hospitalisation: **Age:** 29Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nightmare Agitation Dystonia Insomnia Tremor		Vivid dreams	Zoloft ceased. started cipramil

Medicine Details:

ZOLOFT (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
SERZONE (Interaction)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161417

Seq: 1

Gender: M

Reported: 12/02/2001

Weight:

Hospitalisation:

Age: 80Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aphasia			Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161533

Seq: 1

Gender: F

Reported: 14/02/2001

Weight: 50.00

Hospitalisation:

Age: 48Y

Onset Date: 20/02/2000

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Oedema		Pedal oedema - moderately severe.	
Hypoproteinaemia			

Medicine Details:

RISPERIDONE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started: 03/02/2000	Stopped:	CONTIN
TEMAZEPAM (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started: 03/02/2000	Stopped:	
ZOLOFT (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started: 01/01/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Albumin				Albumin fell to 31.

Additional Information:

Patient also taking lithium and thioridazine. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161558

Seq: 1

Gender: M

Reported: 10/02/2001

Weight: 100.00

Hospitalisation:

Age: 84

Onset Date: 23/01/2001

DOB: 17/05/1916

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Thought disorder	Required a visit to doctor.

Medicine Details:

RISPERDAL (Suspected)		Reason:	
	1.0 Milligram	Daily	
Batch:	Started: 25/12/2000	Stopped: 25/01/2001	
ZOLOFT (Suspected)		Reason:	
	50.0 Milligram	Daily	
Batch:	Started: 24/10/2000	Stopped: 25/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking aldactone, astrix, lanoxin, lasix. patient recovered 28/1/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161582 **Seq:** 1 **Gender:** F
Reported: 16/02/2001 **Weight:** 85.00
Hospitalisation: Admitted to hospital **Age:** 74
Onset Date: 15/01/2001 **DOB:** 29/07/1926
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Irrational behaviour, aggressive.	Cessation of drugs, patient hospitalised
Thinking abnormal		Thought disorder	

Medicine Details:

RISPERDAL (Suspected)	Reason:
2.0 Milligram Daily	
Batch:	Started: 12/02/2000 Stopped: 20/01/2001
ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 19/10/2000 Stopped: 20/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fosamax, augmentin forte, astrix.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161631 **Seq:** 1 **Gender:** M
Reported: 16/02/2001 **Weight:**
Hospitalisation: **Age:** 75Y
Onset Date: 18/11/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Stop zoloft.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 27/10/2000 Stopped: 18/11/2000
TIMENTIN (Suspected)	Reason: Agranulocytosis
12.4 Gram Daily	
Batch:	Started: 04/11/2000 Stopped: 23/11/2000
ACICLOVIR (Suspected)	Reason:
150.0 Milligram Daily	
Batch:	Started: 08/11/2000 Stopped: 23/11/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	GGT = SGGT =	< 50	17/11/2000	490	
	LDH	110-250	17/11/2000	473	
	SAP = ALP	40-110	17/11/2000	810	

Additional Information:

Patient also taking paracetamol, coloxyl with senna, folic acid, multivitamin, ranitidine, allopurinol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161819 **Seq:** 1 **Gender:** M
Reported: 23/02/2001 **Weight:**
Hospitalisation: **Age:** 71Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor		Both hands, worse on initiation of activities.	
Insomnia		Frequent awakenings during the night.	
Diarrhoea		Loose bowels.	
Headache		Tension type over whole head, worse	
Flatulence			

Medicine Details:

ZYBAN SR (Suspected)		Reason: Smoker
	2.0 Dose Unspecified Daily	
Batch:	Started: 01/02/2001	Stopped: CONTIN
ZOLOFT (Suspected)		Reason: Depression
	50.0 Milligram Daily	
Batch:	Started: 01/02/2000	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking norvasc, matrilix, avapro and colofac. sequelae: still smokes 4 cigarettes per day. no previous history of peripheral tremor, headache or insomnia. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161850 **Seq:** 1 **Gender:** F
Reported: 23/02/2001 **Weight:**
Hospitalisation: **Age:** 92Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glaucoma			Reduced zolofit to 25mg every second day.

Medicine Details:

MINITRAN (Other drug)		Reason:	
Cream	0.0	Transdermal	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				One eye 24 and the other eye 18 asymptomatic.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161855 **Seq:** 1 **Gender:** M
Reported: 23/02/2001 **Weight:**
Hospitalisation: **Age:** 55Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			Zoloft was ceased. pt taken to mental health centre.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking lasix, diabex, adalat.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161856 **Seq:** 1 **Gender:** F
Reported: 23/02/2001 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: 01/09/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Agitation Anxiety Chest pain Flushing Hypertension Palpitations		Very jittery tense hands	Ceased zoloft

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161877

Seq: 1

Gender: F

Reported: 23/02/2001

Weight:

Hospitalisation:

Age: 50Y

Onset Date: 31/01/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Developed a stutter	

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking alprazolam. - the date of onset is not necessarily accurate but indicates that onset occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161888

Seq: 1

Gender: M

Reported: 26/02/2001

Weight: 64.00

Hospitalisation:

Age: 71

Onset Date: 01/02/2001

DOB: 03/09/1929

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms		Leg/calf cramps & main diaconcheur of	Zoloft ceased, required a visit to doctor.
Hyperhidrosis			
Nausea			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 161979 **Seq:** 1 **Gender:** U
Reported: 27/02/2001 **Weight:**
Hospitalisation: **Age:** 60
Onset Date: 15/01/2001 **DOB:** 11/12/1940
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction			Zoloft dropped to lower dose.
Rash maculo-papular			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking tofranil, ogen and provera.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162233 **Seq:** 1 **Gender:** F
Reported: 05/03/2001 **Weight:**
Hospitalisation: **Age:** 50Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Ceased zoloft.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162234 **Seq:** 1 **Gender:** M
Reported: 05/03/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 30Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Patient was hospitalised.

Medicine Details:

TEGRETOL (Interaction)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Interaction)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/11/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started on 50mg zoloft in early november 2000, then increased to 100mg at this time tegretol 200mg bd was decreased to 100mg bd. the patient experienced a grand mal seizure. the dosage start date is not necessarily accurate but indicates that start occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162465

Seq: 1

Gender: F

Reported: 14/03/2001

Weight: 72.00

Hospitalisation:

Age: 32

Onset Date: 05/11/2000

DOB: 09/07/1968

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Cough		Persistent irritating dry cough mainly	Date of recovery 13/03/2001. required several visits to

Medicine Details:

MICROVAL (Other drug)		Reason: Contraception
1.0 Dose Unspecified 1 time		
Batch:	Started: 01/01/1999	Stopped: CONTIN
ZOLOFT (Suspected)		Reason: Depression
50.0 Milligram Daily		
Batch:	Started: 05/10/2000	Stopped: 15/02/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous allergies. relevant history - had cxr, bloods, trials of zantac and flixotide. the dose start date of other drug - microval is not necessarily accurate but indicates the drug was started sometimes in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162583 **Seq:** 1 **Gender:** F
Reported: 09/03/2001 **Weight:**
Hospitalisation: **Age:** 92Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Glaucoma			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162798 **Seq:** 1 **Gender:** F
Reported: 19/03/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 73
Onset Date: **DOB:** 02/06/1927
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Anorexia Weight decreased		Sodium level of 120	Withdrew zoloft and restricted

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect that patient had an inappropriate adh secretion due to zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162814 **Seq:** 1 **Gender:** F
Reported: 19/03/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Hot flush Hyperhidrosis Palpitations		Burning sensation on her body.	Patient was hospitalised.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162815 **Seq:** 1 **Gender:** F
Reported: 19/03/2001 **Weight:**
Hospitalisation: **Age:** 45Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162816 **Seq:** 1 **Gender:** F
Reported: 19/03/2001 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope		Vasovagal reaction the next morning.	

Medicine Details:

MICARDIS (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had a history of vasovagal reactions.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162842 **Seq:** 1 **Gender:** M
Reported: 15/03/2001 **Weight:**
Hospitalisation: **Age:** 52
Onset Date: 22/12/2000 **DOB:** 17/05/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Anxiety Pruritus		"out of body " experience.	Sertraline ceased. given phenergan and diazepam.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started: 20/12/2000	Stopped: 22/12/2000	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Known to have had previous allergies before. patient also taking - abacavir, stavudine, nelfinavir, loperamide and temazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 162914

Seq: 1

Gender: F

Reported: 22/03/2001

Weight: 105.00

Hospitalisation:

Age: 44

Onset Date: 01/03/2001

DOB: 20/03/1956

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Rectal haemorrhage		20 motions (watery)/day	Zoloft ceased. date of recovery 09/03/01.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 28/02/2001	Stopped: 07/03/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking betaloc, stelazine, tritace, li co3.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163015 **Seq:** 1 **Gender:** F
Reported: 22/03/2001 **Weight:**
Hospitalisation: **Age:** 28Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Yawning	Severe	Severe yawning attacks.	Changed drug, another ssri was given and this side effect was considerably less with the new drug. required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
	1.0 Dose Unspecified Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had previously been treated with zoloft, successfully. when patient needed further treatment some years later zoloft was again tried.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163073 **Seq:** 1 **Gender:** F
Reported: 22/03/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** A8
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Pain Abdominal pain Atrial fibrillation Consciousness fluctuating Diarrhoea Hypoglycaemia Hyponatraemia Nausea Shock Vomiting		Generalised pain	Patient hospitalised and given

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction)		Reason: Depression
Tablet	0.0	Oral
Batch:	Started:	Stopped:
ARICEPT (Interaction)		Reason: Presenile dementia
Tablet	10.0 Milligram	Daily Oral
Batch:	Started:	Stopped: 16/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Albumin		16/03/2000	32	Ecg - initial sinus bradycardia, then rapid atrial fibrillation. Thyroid function test - 0.4
	Creatine kinase		16/03/2000	70	
	Electrocardiograph				
	Other data				
	Potassium		16/03/2000	52	
	Serum glucose		16/03/2000	9.1	
	Serum osmolality		16/03/2000	526	

Additional Information:

Patient also taking ranitidine, folic acid, pancrease, vitamin b complex, pericyazine, haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163073

Seq: 1

Gender: F

Reported: 22/03/2001

Weight:

Hospitalisation: Admitted to hospital

Age: A8

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Interaction)		Reason:	Depression
Tablet	0.0		Oral
Batch:	Started:		Stopped:
ARICEPT (Interaction)		Reason:	Presenile dementia
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:		Stopped: 16/03/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		16/03/2000	155	After admission 129

Additional Information:

Patient also taking ranitidine, folic acid, pancrease, vitamin b complex, pericyazine, haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163082 **Seq:** 1 **Gender:** F
Reported: 23/03/2001 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dehydration Drug ineffective			Dapa-tabs ceased and efficacy of zoloft returned.

Medicine Details:

ZOLOFT (Interaction)		Reason:
Tablet	0.0	Oral
Batch:	Started:	Stopped:
DAPA-TABS (Interaction)		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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163127 **Seq:** 1 **Gender:** F
Reported: 21/03/2001 **Weight:**
Hospitalisation: **Age:** 34
Onset Date: 06/07/2000 **DOB:** 18/05/1966
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation neonatal		Facial grimacing	
Hypertonia		Leg stiffness	
Neonatal disorder			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
75.0 Milligram	Daily
Batch:	Started: 08/06/2000 Stopped: 28/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Baby displayed facial grimacing and leg stiffness whilst mother was breast feeding and taking zoloft. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163132 **Seq:** 1 **Gender:** F
Reported: 29/03/2001 **Weight:**
Hospitalisation: **Age:** 46
Onset Date: **DOB:** 09/04/1954
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
150.0 Milligram	Daily
Batch:	Started: 01/01/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking metformin, pravachol. the dose start date is not accurate but indicates the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163152

Seq: 1

Gender: M

Reported: 29/03/2001

Weight: 64.00

Hospitalisation:

Age: 44

Onset Date: 02/03/2001

DOB: 28/09/1956

Outcome: Recovered

Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Nocturnal sweating	Required a visit to doctor. date of recovery 10/03/01.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction ceased with withdrawal of drug but returned after reintroduction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163280 **Seq:** 1 **Gender:** U
Reported: 02/04/2001 **Weight:**
Hospitalisation: **Age:** 79
Onset Date: 20/03/2001 **DOB:** 22/01/1922
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bradykinesia			

Medicine Details:

ZOLOFT (Suspected)	Reason:		
	25.0 Milligram	Daily	
Batch:	Started: 17/03/2001	Stopped: 20/03/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking madopar, ditropan, solprin, lipitor. patient recovered 29/3/01. known parkinsons disease.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163356 **Seq:** 1 **Gender:** F
Reported: 30/03/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 18Y
Onset Date: 10/03/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Patient was hospitalised. zoloft ceased. a neurologist has put the patient on anticonvulsant therapy
Headache			

Medicine Details:

PARACETAMOL (Other drug)		Reason: Migraine	
Tablet	1.0 Dose Unspecified	As necessary	Oral
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	7W

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has no history of seizure but does have a history of migraines.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163425 **Seq:** 1 **Gender:** F
Reported: 05/04/2001 **Weight:** 52.00
Hospitalisation: **Age:** 19
Onset Date: 28/11/2000 **DOB:** 13/07/1981
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Acne		Cystic acne.	Required a visit to doctor. zolof ceased. date of recovery: 04/11/2001

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	200.0 Milligram	Daily
Batch:	Started:	04/10/2000
	Stopped:	23/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No prior history of acne. 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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163761 **Seq:** 1 **Gender:** F
Reported: 17/04/2001 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 83
Onset Date: 03/04/2001 **DOB:** 17/08/1917
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Life threatening reaction	Patient hospitalised icu admission. date of recovery 05/04/01

Medicine Details:

PANADEINE FORTE (Other drug)		Reason:	
Batch:	0.0	Started:	Stopped:
DI-GESIC (Other drug)		Reason:	
Batch:	0.0	Started:	Stopped:
THYROXINE SODIUM (Other drug)		Reason:	
Oral application	150.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Oral application	50.0 Milligram	Daily	Oral
Batch:	Started: 28/03/2001	Stopped: 03/04/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		03/04/2001	106MMOL/L	

Additional Information:

Recently commenced on sertraline 50mg daily. no previous exposure to it.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163761 **Seq:** 1

Gender: F

Reported: 17/04/2001

Weight: 60.00

Hospitalisation: Admitted to hospital

Age: 83

Onset Date: 03/04/2001

DOB: 17/08/1917

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

CIMETIDINE (Suspected)

Reason:

400.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

Recently commenced on sertraline 50mg daily. no previous exposure to it.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163893 **Seq:** 1 **Gender:** U
Reported: 23/04/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertension			

Medicine Details:

DIAZEPAM (Other drug)	Reason: Anxiety neurosis
1.0 Dose Unspecified As necessary	
Batch:	Started: Stopped:
MONOPRIL (Suspected)	Reason: Essential benign hypertension
10.0 Milligram Daily	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: Stopped:
TRAMAL (Suspected)	Reason: Other disturbance of sensation
150.0 Milligram Daily	
Batch:	Started: 23/03/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 163893

Seq: 1

Gender: U

Reported: 23/04/2001

Weight:

Hospitalisation: Admitted to hospital

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

CELEBREX (Suspected)

Reason:

100.0 Milligram

Daily

Batch:

Started: 14/11/2000

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164109 **Seq:** 1 **Gender:** U
Reported: 30/04/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 18/04/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis			Patient was hospitalised, fluids, monitoring. date of recovery: 24/4/2001.

Medicine Details:

SODIUM VALPROATE (Suspected)	Reason: Unspecified affective psychosis
1.0 Gram Daily Batch: Started: 01/09/2000 Stopped: 18/04/2001	
OLANZAPINE (Suspected)	Reason: Unspecified schizophrenia
10.0 Milligram Daily Batch: Started: 01/09/2000 Stopped: 18/04/2001	
SERTRALINE HYDROCHLORIDE (Suspected)	Reason: Unspecified schizophrenia
50.0 Milligram Daily Batch: Started: 01/09/2000 Stopped: 18/04/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start dates for sodium valproate, olanzapine and sertraline are not necessarily accurate but indicates these drugs were started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164174 **Seq:** 1 **Gender:** F
Reported: 17/04/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Failure to thrive Vomiting neonatal Weight decreased		Failure to thrive	Hospitalised at 7 months

Medicine Details:

ZOLOFT (Suspected)	Reason:		
	200.0 Milligram	Daily	Breast milk transfer
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Female baby, age 7 months, has been observed for failure to thrive. The baby's current weight is 6.5 kilograms and is being breastfed 4 times a day. The mother is receiving Zolof 200mg/daily. The mother took zolof 100mg/daily during pregnancy. The baby has been hospitalised today due to failure to thrive and vomiting. Besides Zolof, the mother is not receiving any other medication. It is unknown whether the baby is receiving any other medication or has other medical illnesses.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164212 **Seq:** 1 **Gender:** F
Reported: 03/05/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 88
Onset Date: 09/02/2001 **DOB:** 11/04/1912
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Haloperidol. lasix and zolofit ceased. pt hospitalised

Medicine Details:

TRANSIDERM-NITRO (Other drug)		Reason:	
	0.0		
Batch:	Started: 12/01/2001	Stopped:	
LANOXIN PG (Other drug)		Reason:	
Oral application	2.0 Dose Unspecified Daily	Oral	
Batch:	Started: 12/01/2001	Stopped:	
NORVASC (Other drug)		Reason:	
Tablet	2.5 Milligram Daily	Oral	
Batch:	Started: 12/01/2001	Stopped:	
CHLORVESCANT (Other drug)		Reason:	
Oral application	2.0 Dose Unspecified Daily	Oral	
Batch:	Started: 12/01/2001	Stopped: 12/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Chloride		09/02/2001	86	
	Creatinine		09/02/2001	3.0	
	Potassium		09/02/2001	3.7	
	Sodium		09/02/2001	119	
	Urea		09/02/2001	21	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164212 Seq: 1

Gender: F

Reported: 03/05/2001

Weight:

Hospitalisation: Admitted to hospital

Age: 88

Onset Date: 09/02/2001

DOB: 11/04/1912

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

LASIX (Suspected)		Reason:	
Oral application	1.0 Dose Unspecified Daily	Oral	
Batch:	Started: 12/01/2001	Stopped: 09/02/2001	
ZOLOFT (Suspected)		Reason:	
Tablet	25.0 Milligram Daily	Oral	
Batch:	Started: 01/02/2001	Stopped: 09/02/2001	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164301 Seq: 1

Gender: F

Reported: 07/05/2001

Weight: 46.00

Hospitalisation:

Age: 43

Onset Date: 01/12/2000

DOB: 19/03/1957

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea			Required a visit to doctor
Somnolence			

Medicine Details:

ZOLOFT (Suspected)	Reason:
50.0 Milligram	Daily
Batch:	Started: 01/11/2000
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164345 **Seq:** 1 **Gender:** M
Reported: 07/05/2001 **Weight:**
Hospitalisation: **Age:** 64Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal Extrapyramidal disorder			Sertraline ceased.

Medicine Details:

ACICLOVIR (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
TRIMETHOPRIM-SULFAMETHOXAZOLE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
CLARITHROMYCIN (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ITRACONAZOLE (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Large hepatic mitochondrial dna deletions associated with l-lactic acidosis and highly active antiretroviral therapy.

Additional Information:

Aids2001, vol 15 no 3.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164345

Seq: 1

Gender: M

Reported: 07/05/2001

Weight:

Hospitalisation:

Age: 64Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

MEXILETINE HYDROCHLORIDE (Other drug)		Reason:
Batch:	Started:	Stopped:
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

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THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164568

Seq: 1

Gender: F

Reported: 17/05/2001

Weight: 92.00

Hospitalisation:

Age: 36

Onset Date: 03/05/2001

DOB: 22/08/1964

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Stuttering	
Grand mal convulsion			Date of recovery 04/05/01

Medicine Details:

XANAX (Suspected)		Reason:	
	3.0 Milligram	As necessary	
Batch:	Started: 07/04/1997	Stopped: 03/05/2001	
SEROQUEL (Suspected)		Reason:	
Oral application	400.0 Milligram	Daily	Oral
Batch:	Started: 29/11/2000	Stopped: 03/05/2001	
ZOLOFT (Suspected)		Reason: Anxiety neurosis	
	100.0 Milligram	Daily	
Batch:	Started: 23/03/1999	Stopped: 03/05/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 164713 **Seq:** 1 **Gender:** M
Reported: 21/05/2001 **Weight:** 64.00
Hospitalisation: **Age:** 99U
Onset Date: 01/05/2000 **DOB:**
Outcome: Recovered 05/05/2001 **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Difficulty walking, wobbly leg, knees give	Zoloft withdrawn

Medicine Details:

SERETIDE ACCUHALER NOS (Other drug)	Reason:	Asthma
Batch:	2.0 Dose Unspecified Daily	Started:
ZOLOFT (Suspected)	Reason:	Depression
Batch:	25.0 Milligram Daily	Started: 26/04/2000
		Stopped: 02/05/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164774 **Seq:** 1 **Gender:** M
Reported: 23/05/2001 **Weight:**
Hospitalisation: **Age:** 48
Onset Date: 27/04/2001 **DOB:** 27/01/1953
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Extreme agitation felt he was "going loopy"	Zoloft ceased. date of recovery 30/09/2001.

Medicine Details:

STILNOX (Other drug)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 27/04/2001	Stopped: 28/04/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164792 **Seq:** 1 **Gender:** M
Reported: 25/05/2001 **Weight:**
Hospitalisation: **Age:** 75Y
Onset Date: 01/08/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			Zoloft ceased.

Medicine Details:

PARACETAMOL (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
	50.0 Milligram	Daily	
Batch:	Started: 30/07/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Serum drug level				Blood test taken after the patient's arrest revealed no other drugs (including alcohol - although this is still being confirmed) in his system, besides paracetamol and zoloft.

Additional Information:

In the morning of the 1 august 1999, patient took five (250mg) zoloft tablets to treat an anxiety attack. after this, the patient strangled his wife to death.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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Report Detail

Case Number: 164818 **Seq:** 1 **Gender:** F
Reported: 24/05/2001 **Weight:**
Hospitalisation: **Age:** 82
Onset Date: **DOB:** 08/07/1918
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft ceased. fluid restriction

Medicine Details:

GLIPIZIDE (Other drug)	Reason: Diabetes mellitus
40.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
MAXOR (Other drug)	Reason: Other diseases of esophagus
Capsule 20.0 Milligram Daily Oral	
Batch:	Started: L TERM Stopped:
DISPRIN (Other drug)	Reason: Prophylaxis
150.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
CALCITRIOL (Other drug)	Reason: Osteoporosis
Capsule 0.5 Microgram Daily Oral	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		23/10/2000	135	
	Sodium		17/11/2000	132	
	Sodium		22/11/2000	133	
	Sodium		26/11/2000	133	
	Sodium		01/12/2000	133	
	Sodium		11/12/2000	132	
	Sodium		13/03/2001	131	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164818

Seq: 1

Gender: F

Reported: 24/05/2001

Weight:

Hospitalisation:

Age: 82

Onset Date:

DOB: 08/07/1918

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

PERINDOPRIL (Other drug)	Reason:
4.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
ZOLOFT (Suspected)	Reason: Depression
25.0 Milligram Daily	
Batch:	Started: 03/11/2000 Stopped: 09/03/2001

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164819 **Seq:** 1 **Gender:** M
Reported: 24/05/2001 **Weight:**
Hospitalisation: **Age:** 75
Onset Date: 13/03/2001 **DOB:** 27/05/1925
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Stiffness generalised of upper limbs	Zoloft reduced and ceased. required a visit to doctor.

Medicine Details:

LISINOPRIL (Other drug)	Reason: Essential benign hypertension
20.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
CARDIPRIN 100 (Other drug)	Reason: Chron isch heart dis no hyper
50.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
NORVASC (Other drug)	Reason: Chron isch heart dis no hyper
10.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
SOTALOL HYDROCHLORIDE (Other drug)	Reason:
80.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking sodium valproate, xalatan, coloxyl, panadeine, naprosyn, methyl salicilate. zoloft started on 27/10/00 at 50mg, increased to 100mg on 26/12/00, increased again to 150mg on 13/03/00.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164819

Seq: 1

Gender: M

Reported: 24/05/2001

Weight:

Hospitalisation:

Age: 75

Onset Date: 13/03/2001

DOB: 27/05/1925

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

PERSANTIN SR (Other drug)		Reason:	Prophylaxis
	200.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
ZOLOFT (Suspected)		Reason:	Depression
	150.0 Milligram	Daily	
Batch:	Started: 13/03/2000	Stopped:	20/03/2001

Laboratory Investigations:

Additional Information:

Patient also taking sodium valproate, xalatan, coloxyl, panadeine, naprosyn, methyl salicilate. zoloft started on 27/10/00 at 50mg, increased to 100mg on 26/12/00, increased again to 150mg on 13/03/00.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164820

Seq: 1

Gender: U

Reported: 24/05/2001

Weight: 60.00

Hospitalisation:

Age: 44

Onset Date: 02/01/2001

DOB: 25/05/1956

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Sertraline ceased. date of recovery 10/01/01.

Medicine Details:

DONEPEZIL HYDROCHLORIDE (Other drug)		Reason:	Presenile dementia
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Other drug)		Reason:	Otr spec symp psychopathol nec
Oral application	1.0 Milligram	Daily	Oral
Batch:	Started: 14/11/2000	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	Depression
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 05/12/2000	Stopped: 10/01/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164836

Seq: 1

Gender: F

Reported: 25/05/2001

Weight: 70.00

Hospitalisation:

Age: 50

Onset Date: 15/05/2001

DOB: 23/11/1950

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypotension	Life threatening	Intra and postoperative hypotension 50-60 mmHg	Required aramine infusion intraoperatively and post op for 2 days to maintain bp (laparotomy). date of recovery: 17/5/2001

Medicine Details:

ZOTON (Other drug)	0.0	Reason: Other diseases of esophagus
Batch:	Started:	Stopped:
CALTRATE (Other drug)	0.0	Reason:
Batch:	Started:	Stopped:
PHYTOMENADIONE (Other drug)	0.0	Reason:
Batch:	Started:	Stopped:
OROXINE (Other drug)	0.0	Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking hrt.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 164836

Seq: 1

Gender: F

Reported: 25/05/2001

Weight: 70.00

Hospitalisation:

Age: 50

Onset Date: 15/05/2001

DOB: 23/11/1950

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason:	Depression
Batch:	Started:	Stopped: 15/05/2001
ENALAPRIL MALEATE (Suspected)	Reason:	Essential benign hypertension
Batch:	Started:	Stopped: 15/05/2001

Laboratory Investigations:

Additional Information:

Patient also taking hrt.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164971 **Seq:** 1 **Gender:** F
Reported: 30/05/2001 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: 28/05/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Threatened her sibling with a screwdriver.	

Medicine Details:

ZOLOFT (Suspected)		Reason: Obsessive compulsive neurosis	
Tablet	150.0 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. patient had been maintained on 100mg per day. physician attempted to cease zoloft therapy however ocd symptoms recurred. about 2 months ago zoloft was restarted and dose increased to 150mg per day, as ocd symptoms were not manageable at 100mg per day.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 164972 **Seq:** 1 **Gender:** F
Reported: 30/05/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 28/11/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/11/2000	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 the month. the dose start date is not necessarily accurate but indicates the drug was started sometime in the month. dose increased to 100mg per day and patient's agitation continued and worsened.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 164979 **Seq:** 1 **Gender:** F
Reported: 16/05/2001 **Weight:**
Hospitalisation: **Age:** AD
Onset Date: 25/12/1999 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypokinesia Coordination abnormal Neonatal disorder Tremor		Delayed in motor development.	

Medicine Details:

PREDNISONE (Suspected)	Reason: Systemic lupus erythematosus
0.0	
Batch:	Started: Stopped:
NARCOTIC NOS (Suspected)	Reason: Pain
0.0	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason: Depression
Tablet 200.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Mother on zoloft for depression 200mg as well prednisone for lupus during preg nancy. the child has had tremors, delayed in motor development - with possible ataxia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

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Report Detail

Case Number: 164998 **Seq:** 1 **Gender:** F
Reported: 30/05/2001 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 15Y
Onset Date: 31/12/1999 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Bipolar disorder Agitation		Manic depressive psychosis	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Pt started zoloft at 50mg/d then increased dose to 100mg/d. The date of onset is not accurate but indicated onset sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165028 **Seq:** 1 **Gender:** F
Reported: 31/05/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 50Y
Onset Date: 27/07/1997 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Mania			Pt hospitalised for 5 days. zoloft ceased. treated with other drugs for manic episode.

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started:	01/03/1997
	Stopped:	31/07/1997

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165143 **Seq:** 1 **Gender:** M
Reported: 04/06/2001 **Weight:**
Hospitalisation: **Age:** 38
Onset Date: 31/12/1998 **DOB:** 29/06/1960
Outcome: Not yet recovered **Causality:** Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation Hyperhidrosis			Zoloft and valium ceased.

Medicine Details:

VALIUM (Other drug)		Reason:	
Oral application	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	2M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous exposure to zoloft in 1995 produced same reaction.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165199 **Seq:** 1 **Gender:** F
Reported: 07/06/2001 **Weight:** 56.00
Hospitalisation: **Age:** 39
Onset Date: 28/05/2001 **DOB:** 09/08/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria			Zoloft ceased. treated with aristocort 0.02% and claratyne 1 daily. required a visit to doctor

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 21/05/2001	Stopped: 30/05/2001	
ZYBAN SR (Suspected)		Reason: Smoker	
	2.0 Dose Unspecified	Daily	
Batch:	Started: 21/05/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165284 **Seq:** 1 **Gender:** F
Reported: 12/06/2001 **Weight:**
Hospitalisation: **Age:** 30
Onset Date: **DOB:** 07/12/1970
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

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

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Took about 6 weeks to recovery.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165329 **Seq:** 1 **Gender:** F
Reported: 12/06/2001 **Weight:**
Hospitalisation: **Age:** 33Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dysphagia			

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Tablet	0.0	Daily	Oral
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past history - brain injury.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165367 **Seq:** 1 **Gender:** F
Reported: 04/06/2001 **Weight:**
Hospitalisation: **Age:** 53Y
Onset Date: 28/05/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematuria		Passing blood in urine.	
Urinary retention			

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 18/06/1998	Stopped:	18/08/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165375 **Seq:** 1 **Gender:** M
Reported: 07/06/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient was hospitalised

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	600.0 Milligram	Total	Oral
Batch:	Started:	Stopped:	
NALTREXONE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	20.0 Dose Unspecified	Total	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also had 15 schooners of beer.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165413 **Seq:** 1 **Gender:** F
Reported: 14/06/2001 **Weight:** 64.00
Hospitalisation: **Age:** 51
Onset Date: 02/06/2001 **DOB:** 08/07/1949
Outcome: Death **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coma			
Convulsion			
Encephalopathy			
Sudden death			

Medicine Details:

CESIUM CHLORIDE (Interaction)	Reason:
0.0	
Batch:	Started: 31/05/2001 Stopped:
ZOLOFT (Interaction)	Reason:
0.0	
Batch:	Started: Stopped:
MAXOLON (Interaction)	Reason:
0.0	Oral
Batch:	Started: Stopped:
TEMAZEPAM (Interaction)	Reason:
0.0	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient thought to have serotonin encephalopathy, no evidence of 2nd ca on ct or mri.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165514 **Seq:** 1 **Gender:** F
Reported: 01/06/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 49Y
Onset Date: 17/02/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Epistaxis			Patient was hospitalised. patient required cautery and packing on 3 different occasions. ceased celebrex.
Hypertension			

Medicine Details:

TEMAZE (Other drug)		Reason:	
	0.0		
Batch:	Started: 02/07/1999	Stopped:	CONTIN
CELEBREX (Suspected)		Reason:	
Capsule	200.0 Milligram	Daily	Oral
Batch:	Started: 05/06/2000	Stopped:	17/02/2001
SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	2.0 Dose Unspecified	Daily	Oral
Batch:	Started: 10/05/2000	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165549 **Seq:** 1 **Gender:** M
Reported: 15/06/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

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

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/11/1999	Stopped:	06/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start is not necessarily accurate but indicates zoloft was started sometime in the month. patient recovered 8/6/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165559 **Seq:** 1 **Gender:** F
Reported: 14/06/2001 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Erythematous lumps on lower legs.	
Hyperhidrosis		Night sweats	
Oedema		Swelling in legs, knees and ankles.	
Fatigue			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 01/11/1999 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started taking zoloft 50mg daily, the dose was gradually increased to 150mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165573

Seq: 1

Gender: F

Reported: 18/06/2001

Weight: 74.00

Hospitalisation:

Age: 76

Onset Date: 07/05/2001

DOB: 26/08/1924

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Hallucination Nightmare			Required a visit to doctor. zoloft ceased.

Medicine Details:

ZOLOFT (Interaction)	100.0 Milligram	Daily	Reason: Depression
Batch:	Started: 11/06/1994	Stopped:	
ARICEPT (Interaction)	5.0 Milligram	Daily	Reason:
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This patient initially had no side effects from zoloft alone but recently developed reactions whilst on both aricept and zoloft. no change to symptoms when aricept decreased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165576

Seq: 1

Gender: F

Reported: 04/06/2001

Weight: 100.00

Hospitalisation:

Age: 52

Onset Date: 01/02/2001

DOB: 08/08/1948

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle spasms	Severe	Severe persistent muscle cramps.	Required a visit to doctor. date of recovery 26.2.01. zoloft and celebrex ceased.

Medicine Details:

ZOLOFT (Interaction)	Reason:
50.0 Milligram Daily	
Batch:	Started: Stopped:
CELEBREX (Interaction)	Reason:
400.0 Milligram Daily	
Batch:	Started: Stopped:
MODURETIC (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

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165576

Seq: 1

Gender: F

Reported: 04/06/2001

Weight: 100.00

Hospitalisation:

Age: 52

Onset Date: 01/02/2001

DOB: 08/08/1948

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

STEMETIL (Other drug)	Reason:
Batch:	1.0 Dose Unspecified As necessary
Started:	Stopped:
PREMIA 5 CONTINUOUS (Other drug)	Reason:
Batch:	1.0 Dose Unspecified Daily
Started:	L TERM Stopped:
TENORMIN (Other drug)	Reason:
Batch:	50.0 Milligram Daily
Started:	L TERM Stopped:
ZANTAC (Other drug)	Reason:
Batch:	300.0 Milligram Daily
Started:	L TERM Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165971 **Seq:** 1 **Gender:** F
Reported: 29/06/2001 **Weight:** 63.00
Hospitalisation: Admitted to hospital **Age:** 53Y
Onset Date: 09/06/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state Diarrhoea Haematemesis Hyperhidrosis Nausea Rash Renal pain Vomiting			Zoloft ceased. treated with iv fluids, omeprazole and iv gentamicin. patient was hospitalised

Medicine Details:

ASPIRIN (Other drug)	Reason:
300.0 Milligram Weekly	
Batch:	Started: Stopped:
RAMIPRIL (Other drug)	Reason:
10.0 Milligram Daily	
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason:
150.0 Milligram Daily	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 09/06/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Sequelae: slight dizziness persisted till 24.6.01. allergies: stemetil.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 165977

Seq: 1

Gender: F

Reported: 18/06/2001

Weight: 3.00

Hospitalisation:

Age: AD

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Congenital hand malformation			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Other data				Absent middle and ring fingers, hypoplastic index finger, hypoplastic little finger and possibly mildly small thumb.

Additional Information:

Other drugs prescribed: 'antibiotics' & steroids 2 weeks early trimester one. teratogenic effect right hand - absent middle and ring fingers, hypoplastic index finger, hypoplastic little finger and possibly mildly small thumb.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166082

Seq: 1

Gender: F

Reported: 03/07/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amnesia		Didn't remember sleep walking.	
Fatigue		Excessively tired.	
Depersonalisation		Had the appearance of being "spaced out".	
Sleep walking		Happened about a dozen times over 18	
Somnolence		-----	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166320 **Seq:** 1 **Gender:** F
Reported: 11/07/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 33Y
Onset Date: 28/05/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depersonalisation Hypoaesthesia Convulsion Amnesia		"funny feeling" in head and feeling vague. Numbness in left arm/elec shock from head Seizure	Patient was hospitalised. zoloft dose was dropped to 50mg/day for two weeks and 50mg every second day for one week and the last dose was taken on 17/6/01.

Medicine Details:

ZOLOFT (Suspected)	Reason: Anxiety neurosis
Tablet	100.0 Milligram Daily Oral
Batch:	Started: 01/02/2001 Stopped: 17/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The date of onset is not necessarily accurate but indicates onset sometime in the month. the dose start date is not necessarily accurate but indicates zoloft was started sometime in the month. patient has had a hysterectomy due to guillian-barr infection in 1998 and a benign cyst.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166326 **Seq:** 1 **Gender:** M
Reported: 11/07/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure	Severe	Severe.	

Medicine Details:

ZOLOFT (Suspected)		Reason: Behavior disorders of childhood	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166343

Seq: 1

Gender: F

Reported: 11/07/2001

Weight: 55.00

Hospitalisation:

Age: 30Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Alcoholism		Experienced alcohol cravings	
Weight increased		Put on 10 kilos	

Medicine Details:

TRAMAL (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
DI-GESIC (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily Oral
Batch:	Started: 01/01/1999 Stopped: 15/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for Zoloft is not accurate but indicated the drug was commenced sometime in 1999.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166344 **Seq:** 1 **Gender:** F
Reported: 11/07/2001 **Weight:**
Hospitalisation: **Age:** 30Y
Onset Date: 28/02/2001 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Patient has not menstrated for the past	Plans to cease zoloft if event do not resolve
Hyperprolactinaemia			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 27/02/2001	Stopped:	15/06/2001
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Prolactin Radiology				Prolactin level of 3000 plus. Mri scan was performed which revealed a microadenoma.

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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166367 **Seq:** 1 **Gender:** M
Reported: 11/07/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Speech disorder			

Medicine Details:

ENDEP (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
0.0	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166403

Seq: 1

Gender: M

Reported: 13/07/2001

Weight:

Hospitalisation:

Age: 36

Onset Date: 05/07/2001

DOB: 21/09/1964

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Periorbital oedema		Swelling below eyes.	
Face oedema		Swelling of lips (not tongue).	Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 02/07/2001 Stopped: 07/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reactions would appear overnight and recede by day.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166452 **Seq:** 1 **Gender:** U
Reported: 16/07/2001 **Weight:** 69.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 28/06/2001 **DOB:** 11/10/1965
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Tremor Paraesthesia Dysarthria Thinking abnormal Asthenia Hot flush Nausea Somnolence		Shaky legs. Tingling left arm and side of face. Unable to speak properly. Vocing thought.	Zoloft ceased. admitted to hospital. still recovering 04/07/2001

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 26/06/2001 Stopped: 30/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166653

Seq: 1

Gender: M

Reported: 19/07/2001

Weight: 65.00

Hospitalisation:

Age: 21

Onset Date: 06/07/2001

DOB: 16/12/1979

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability		Emotionally volubilable	Risperidone 1 mg bd. required a visit to doctor. sertraline reduced to 25mg/day for 2 weeks then stopped
Thinking abnormal		Thought disorder	
Delusion			
Paranoia			
Psychotic disorder			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression
	50.0 Milligram	Daily
Batch:	Started: 21/12/1999	Stopped: 30/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 13/7/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166837 **Seq:** 1 **Gender:** M
Reported: 25/07/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 06/07/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		Excess movement in arms and legs.	
Vertigo		Spinny feeling while lying down.	
Anxiety			Zoloft ceased
Depersonalisation			

Medicine Details:

ZOLOFT (Suspected)	Reason: Behavior disorders of childhood
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 06/07/2001 Stopped: 13/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking ritalin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 166841 **Seq:** 1 **Gender:** M
Reported: 25/07/2001 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: 25/06/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Had hit mother.	Zoloft was ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression
Tablet	0.0	Oral
Batch:	Started:	Stopped: 1W
METHADONE HYDROCHLORIDE (Suspected)		Reason:
	0.0	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166993 **Seq:** 1 **Gender:** F
Reported: 30/07/2001 **Weight:** 60.00
Hospitalisation: Admitted to hospital **Age:** 86
Onset Date: 22/07/2001 **DOB:** 16/06/1915
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Hyponatraemia			Patient was hospitalised. date of recovery 27.7.01.

Medicine Details:

OMEPRAZOLE (Other drug)	Reason: Peptic ulcer nos w/o ment perf
20.0 Milligram Daily	
Batch:	Started: Stopped:
IRBESARTAN (Other drug)	Reason: Essential benign hypertension
150.0 Milligram Daily	
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
10.0 Milligram Daily	
Batch:	Started: Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason: Diabetes mellitus
250.0 Milligram Daily	
Batch:	Started: Stopped: 25/07/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 166993

Seq: 1

Gender: F

Reported: 30/07/2001

Weight: 60.00

Hospitalisation: Admitted to hospital

Age: 86

Onset Date: 22/07/2001

DOB: 16/06/1915

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)

Reason: Depression

50.0 Milligram

Daily

Batch:

Started:

Stopped: 21/07/2001

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167106 **Seq:** 1 **Gender:** F
Reported: 02/08/2001 **Weight:** 70.00
Hospitalisation: **Age:** 31
Onset Date: 24/02/2001 **DOB:** 31/03/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion Nausea			Required a visit to doctor. date of recovery 30.3.01 zyban

Medicine Details:

ZYBAN SR (Interaction)	Reason:
0.0	
Batch:	Started: 20/02/2001 Stopped:
ZOLOFT (Interaction)	Reason: Depression
200.0 Milligram Daily	
Batch:	Started: 01/09/1999 Stopped:
TRIFEME 28 (Other drug)	Reason: Contraception
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for zoloft is not necessarily accurate but indicates the drug was started sometime in the month. occasional jerky movements in legs, arms at rest starting within day of starting zyban.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167146 **Seq:** 1 **Gender:** F
Reported: 01/08/2001 **Weight:**
Hospitalisation: **Age:** 35Y
Onset Date: 31/12/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Syncope Tachycardia			Treated with rythmodan.

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason: Myxedema
Tablet	0.0	Oral
Batch:	Started:	Stopped:
ZOLOFT (Suspected)		Reason: Depression
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 01/01/2000	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 for zoloft is not accurate but indicates the drug was started sometime in the year.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167240 **Seq:** 1 **Gender:** F
Reported: 06/08/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 64Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation		Increased agitation.	Patient was hospitalised. zoloft dose increased to 200mg and she has improved.
Neurosis		Obsession with knives.	
Aggression		Threatening to kill her husband.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced zoloft 25mg daily for depression and agitation. after 1 week the dose was increased to 50mg daily. 1 week later patient experienced reactions.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 167241 **Seq:** 1 **Gender:** F
Reported: 06/08/2001 **Weight:**
Hospitalisation: **Age:** 68
Onset Date: 26/07/2001 **DOB:** 02/06/1933
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Zoloft ceased.

Medicine Details:

ZOLOFT (Interaction)		Reason: Depression
Tablet	50.0 Milligram	Daily Oral
Batch:	Started: 18/07/2001	Stopped: 26/07/2001
PHENOBARBITONE (Interaction)		Reason: Other&unspecified epilepsy
Tablet	120.0 Milligram	Daily Oral
Batch:	Started: L TERM	Stopped:
EPILIM (Interaction)		Reason: Other&unspecified epilepsy
Tablet	2.0 Gram	Daily Oral
Batch:	Started: L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Epilepsy since age 11, fit free for 15 years.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167242 **Seq:** 1 **Gender:** F
Reported: 06/08/2001 **Weight:**
Hospitalisation: **Age:** 17Y
Onset Date: 28/07/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Developed buccal lingual movements.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Tablet	0.0 Oral
Batch:	Started: 01/12/1990 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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167245

Seq: 1

Gender: M

Reported: 06/08/2001

Weight:

Hospitalisation:

Age: 43Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Apathy		Patient felt "flat".	Zoloft ceased suddenly of patient's own accord.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	01/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose stop date is not accurate but indicates the drug was stopped sometime around june.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167246 **Seq:** 1 **Gender:** M
Reported: 06/08/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 11Y
Onset Date: 27/06/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Choreoathetosis Speech disorder Agitation Dystonia		Chorea like movements. Developed mutism areoun the 27.6.01.	Patient was hospitalised.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/05/2001	Stopped:	30/06/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167296 **Seq:** 1 **Gender:** F
Reported: 08/08/2001 **Weight:** 93.00
Hospitalisation: **Age:** 56
Onset Date: 03/08/2001 **DOB:** 02/09/1944
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Haematuria			Patient required a visit to a doctor; medications ceased.
Rectal haemorrhage			

Medicine Details:

LIPITOR (Other drug)	Reason:
0.0	
Batch:	Started: L TERM Stopped:
DICHLORIDE (Other drug)	Reason:
0.0	
Batch:	Started: L TERM Stopped:
PREMARIN (Other drug)	Reason:
0.0	
Batch:	Started: L TERM Stopped:
TAGAMET (Other drug)	Reason:
0.0	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered on the 6/8/2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167296

Seq: 1

Gender: F

Reported: 08/08/2001

Weight: 93.00

Hospitalisation:

Age: 56

Onset Date: 03/08/2001

DOB: 02/09/1944

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)

Reason: Depression

Tablet

25.0 Milligram

Daily

Oral

Batch:

Started: 02/08/2001

Stopped:

Laboratory Investigations:

Additional Information:

Patient recovered on the 6/8/2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167299 **Seq:** 1 **Gender:** F
Reported: 08/08/2001 **Weight:**
Hospitalisation: **Age:** A3
Onset Date: 28/07/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Anaphylactoid reaction		Anaphylactic type reaction after 1 dose of	Patient presented to hospital and treated with adrenalin.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
Oral application	25.0 Milligram 1 time 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 occurred after taking 1 dose of zoloft.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167332 **Seq:** 1 **Gender:** F
Reported: 08/08/2001 **Weight:**
Hospitalisation: **Age:** 40Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Weight increased		1999 = 57kg --> now 69 kg.	Diet control and exercise with no effect

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	
Batch:	Started: 01/07/1999	Stopped:	CONTIN
CENTRUM TABLETS (Suspected)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started: L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167422 **Seq:** 1 **Gender:** F
Reported: 13/08/2001 **Weight:** 60.00
Hospitalisation: **Age:** 17
Onset Date: **DOB:** 19/05/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt Agitation Tremor		Wrist slashing	Required a visit to doctor. ceased zoloft and changed to avapro

Medicine Details:

LEVLEN ED (Other drug)		Reason: Contraception
	1.0 Dose Unspecified Daily	
Batch:	Started: 20/11/2000	Stopped: CONTIN
ZOLOFT (Suspected)		Reason: Depression
	150.0 Milligram Daily	
Batch:	Started: 09/10/2000	Stopped: 15/03/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was depressed- increasing zoloft 50mg to 150mg caused symptoms. changed to avapro and changed back to normal behaviour. patient recovered 18/3/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167502 **Seq:** 1 **Gender:** F
Reported: 13/08/2001 **Weight:**
Hospitalisation: **Age:** 83Y
Onset Date: 17/11/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urinary retention			Dose reduced back to 50mg, problem eased but persisted.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2000	Stopped:	28/01/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167584

Seq: 1

Gender: M

Reported: 16/08/2001

Weight:

Hospitalisation:

Age: 17Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason:
Tablet	0.0
Batch:	Started:
	Stopped:
	9M

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167619 **Seq:** 1 **Gender:** M
Reported: 16/08/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Breast pain		Sore enlarged left breast.	

Medicine Details:

PROTHIADEN (Other drug)		Reason:	
	0.0		
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/02/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167625

Seq: 1

Gender: U

Reported: 16/08/2001

Weight: 55.00

Hospitalisation:

Age: 32

Onset Date: 10/08/2001

DOB: 01/09/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Diarrhoea Dry mouth Headache Myalgia Nausea Vomiting			Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
25.0 Milligram	Daily
Batch:	Started: 09/08/2001
	Stopped: 11/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167628

Seq: 1

Gender: F

Reported: 17/08/2001

Weight: 70.00

Hospitalisation:

Age: 20

Onset Date: 04/08/2001

DOB: 30/03/1981

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Fine rash started on torso spreading to	Required a visit to doctor.

Medicine Details:

IRON (Other drug)	reason:	Unspecified anemia
Tablet	0.0	Oral
Batch:	Started:	Stopped:
DEPO-PROVERA (Other drug)	reason:	Contraception
	0.0	
Batch:	Started: 08/01/2001	Stopped:
TRIPRIM (Other drug)	reason:	Othr diseases of urinary tract
	0.0	
Batch:	Started: 08/06/2001	Stopped: 11/06/2001
ZOLOFT (Suspected)	reason:	Depression
	50.0 Milligram	Daily
Batch:	Started: 01/08/2001	Stopped: 14/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167634

Seq: 1

Gender: F

Reported: 17/08/2001

Weight:

Hospitalisation:

Age: 41Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality certain

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Nausea Agitation		Ongoing nausea.	Zoloft continues and the events are still present.

Medicine Details:

ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start date for zoloft is not accurate but indicates the drug was started sometime in the year. nausea begins about 2 hours after ingestion of zoloft and improves if the zoloft is taken after food.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167735

Seq: 1

Gender: M

Reported: 20/08/2001

Weight:

Hospitalisation:

Age: 50Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Agitation			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/11/2000	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient started on 50mg but did not respond and dose increased to 100mg. the dose start date for zoloft is not necessarily accurate but indicates the drug was commenced sometime in november.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167736 **Seq:** 1 **Gender:** F
Reported: 20/08/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 28/10/2000 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient was hospitalised. patient was released with

Medicine Details:

ALCOHOL (Suspected)		Reason:	
Batch:		0.0	Stopped:
Started:			
ZOLOFT (Suspected)		Reason: Depression	
Tablet		150.0 Milligram	Daily Oral
Batch:		Started: 01/10/2000	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 the month. the dose start date for zoloft is not necessarily accurate but indicates the drug was started sometime in the month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 167737 **Seq:** 1 **Gender:** M
Reported: 20/08/2001 **Weight:** 0.00
Hospitalisation: **Age:** 80Y
Onset Date: 26/07/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Suspected SIADH	Zoloft ceased.

Medicine Details:

DIGOXIN (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ALLOPURINOL (Other drug)		Reason:	
Tablet	0.0	Oral	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/07/2001	Stopped: 28/07/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The dose start and stop dates for zoloft are not necessarily accurate but indicates the drug was started and stopped sometime in the month. diagnosed with subacute bacterial endocarditis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167817

Seq: 1

Gender: M

Reported: 23/08/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Agitation			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)	reason:	Depression
Tablet	50.0 Milligram	Daily
Batch:	Started:	Stopped:
		4D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 167853 **Seq:** 1 **Gender:** F
Reported: 24/08/2001 **Weight:**
Hospitalisation: Treated in outpatient department only. **Age:** 17Y
Onset Date: 01/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Convulsion			Zoloft ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168124

Seq: 1

Gender: M

Reported: 05/09/2001

Weight: 88.00

Hospitalisation:

Age: 35

Onset Date: 18/08/2001

DOB: 25/11/1965

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia Conjunctival haemorrhage Headache Photophobia		Paraesthesia fingers. Sub-conjunctival haemorrhage r eye 2 days ---	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 07/07/2001
	Stopped: 19/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 27/8/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168153 Seq: 1

Gender: F

Reported: 03/09/2001

Weight: 54.00

Hospitalisation:

Age: 20

Onset Date: 24/08/2001

DOB: 22/01/1981

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Bilateral galactorrhoea	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
125.0 Milligram	Daily
Batch:	Started: 01/01/1998
	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.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168159 **Seq:** 1 **Gender:** F
Reported: 03/09/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 37Y
Onset Date: 27/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Itchy rash all over body	Patient was admitted to
Arthralgia			
Myalgia			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 01/04/2001	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168231

Seq: 1

Gender: F

Reported: 07/09/2001

Weight: 70.00

Hospitalisation:

Age: 81Y

Onset Date: 22/08/2001

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Delirium			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Anxiety neurosis	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 17/08/2001	Stopped: 03/09/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168245 **Seq:** 1 **Gender:** F
Reported: 07/09/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 86Y
Onset Date: 13/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Patient was admitted to hospital; zolofit was ceased.

Medicine Details:

TAMOXIFEN CITRATE (Other drug)					Reason:	Malignant neoplasm of breast	
Tablet	20.0	Milligram	Daily	Oral			
Batch:	Started:		Stopped:				
ZOLOFT (Suspected)					Reason:	Depression	
Tablet	50.0	Milligram	Daily	Oral			
Batch:	Started:		13/08/2001		Stopped:	14/08/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		14/08/2001	129	

Additional Information:

Patient felt poorly before starting zolofit. patient had a parathyroidectomy and removal of cancer of the right breast by lumpectomy. physician felt patient was dehydrated so instructed patient to increase fluid intake to start zolofit.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168246 **Seq:** 1 **Gender:** F
Reported: 07/09/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 37Y
Onset Date: 26/08/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Generalised urticarial rash all over	Patient was admitted to hospital; zolofit was ceased.
Osteoarthritis		Swelling of fingers and joints	
Back pain			
Pruritus			
Serum sickness			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	27/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168248

Seq: 1

Gender: M

Reported: 07/09/2001

Weight:

Hospitalisation:

Age: 29Y

Onset Date: 25/08/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			Patient required to visit a doctor; zolof is withdrawn.

Medicine Details:

ZOLOFT (Suspected)				Reason:	Depression
Tablet	50.0	Milligram	Daily		Oral
Batch:	Started:	17/04/2001	Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was commenced on 25mg zolof daily and increased to 50mg per day on the 1 may 2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168271

Seq: 1

Gender: F

Reported: 10/09/2001

Weight: 59.00

Hospitalisation:

Age: 56

Onset Date: 08/08/2001

DOB: 05/10/1944

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Face oedema Pruritus		Facial angioedema	Required a visit to doctor.

Medicine Details:

THIAMINE HYDROCHLORIDE (Other drug)	Reason:
Tablet	0.0
Batch:	Started: Stopped: Oral
TISSUE SALTS M11/5X (Other drug)	Reason:
	0.0
Batch:	Started: Stopped:
SPIRULINA (Other drug)	Reason:
	0.0
Batch:	Started: Stopped:
ASCORBIC ACID (Other drug)	Reason:
	0.0
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 11/8/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168271

Seq: 1

Gender: F

Reported: 10/09/2001

Weight: 59.00

Hospitalisation:

Age: 56

Onset Date: 08/08/2001

DOB: 05/10/1944

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)

Reason: Depression

Tablet

50.0 Milligram

1 time

Oral

Batch:

Started: 08/08/2001

Stopped:

Laboratory Investigations:

Additional Information:

Patient recovered 11/8/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168294 **Seq:** 1 **Gender:** F
Reported: 10/09/2001 **Weight:**
Hospitalisation: **Age:** 60Y
Onset Date: 20/07/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression		Extremely aggressive.	Tramadol ceased.
Paranoia		Rude with paranoid behaviour.	

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interaction)		Reason: Pain
Capsule	50.0 Milligram	As necessary Oral
Batch:	Started: 19/07/2001	Stopped: 22/07/2001
ZOLOFT (Interaction)		Reason:
	50.0 Milligram	Daily
Batch:	Started: 12/07/2001	Stopped:
PANADOL (Other drug)		Reason:
	2.0 Dose Unspecified	As necessary
Batch:	Started: 12/07/2001	Stopped:
PANADEINE (Other drug)		Reason:
	2.0 Dose Unspecified	As necessary
Batch:	Started: 12/07/2001	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking norvasc which was added and withheld over several weeks. history: hypercholesterol, hypertension, asthma/bronchitis, depressive illness, arthritis, seasonal hayfever, back problems, knee problems (both).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168294

Seq: 1

Gender: F

Reported: 10/09/2001

Weight:

Hospitalisation:

Age: 60Y

Onset Date: 20/07/2001

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

MAXOLON (Other drug)	Reason:
10.0 Milligram	As necessary
Batch:	Started: 12/07/2001
Stopped:	
TEMAZEPAM (Other drug)	Reason:
10.0 Milligram	As necessary
Batch:	Started: 20/07/2001
Stopped:	
VENTOLIN (Other drug)	Reason:
Inhalation	2.0 Dose Unspecified As necessary Inhalation
Batch:	Started: 12/07/2001
Stopped:	
ENALAPRIL MALEATE (Other drug)	Reason:
30.0 Milligram	Daily
Batch:	Started: 12/07/2001
Stopped:	

Laboratory Investigations:

Additional Information:

Patient also taking norvasc which was added and withheld over several weeks. history: hypercholesterol, hypertension, asthma/bronchitis, depressive illness, arthritis, seasonal hayfever, back problems, knee problems (both).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168294
Reported: 10/09/2001
Hospitalisation:
Onset Date: 20/07/2001
Outcome: Recovered

Seq: 1

Gender: F

Weight:

Age: 60Y

DOB:

Causality: Causality possible

Reaction Detail

Medicine Details:

ATORVASTATIN (Other drug)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started: 12/07/2001	Stopped:	
PREMARIN (Other drug)		Reason:	
	625.0 Microgram	Daily	
Batch:	Started: 12/07/2001	Stopped:	
BECOTIDE (Other drug)		Reason:	
Inhalation	4.0 Dose Unspecified	Daily	Inhalation
Batch:	Started: 12/07/2001	Stopped:	
CLEXANE (Other drug)		Reason:	
Injection	40.0 Milligram	Daily	Subcutaneous
Batch:	Started: 17/07/2001	Stopped:	

Laboratory Investigations:

Additional Information:

Patient also taking norvasc which was added and withheld over several weeks. history: hypercholesterol, hypertension, asthma/bronchitis, depressive illness, arthritis, seasonal hayfever, back problems, knee problems (both).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168478

Seq: 1

Gender: F

Reported: 18/09/2001

Weight: 57.00

Hospitalisation:

Age: 40

Onset Date: 21/06/2001

DOB: 15/06/1961

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Muscle twitching Anxiety Dry mouth Headache Insomnia Nervousness Tremor		Eye flickering.	Date of recovery 10/07/2001.

Medicine Details:

IMPLANON IMPLANT (Suspected)	Reason:
0.0	
Batch:	Started: 28/05/2001 Stopped:
ZYBAN SR (Suspected)	Reason: Smoker
Tablet	2.0 Dose Unspecified Daily Oral
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168498

Seq: 1

Gender: M

Reported: 17/09/2001

Weight: 65.00

Hospitalisation:

Age: 19

Onset Date: 30/08/2001

DOB: 02/01/1982

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Urticaria		Extensive rash over trunk and abdomen.	
Vomiting			Required a visit to doctor.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168594

Seq: 1

Gender: F

Reported: 24/09/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia			Zoloft was ceased.

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168661

Seq: 1

Gender: M

Reported: 24/09/2001

Weight: 56.00

Hospitalisation:

Age: 22

Onset Date: 19/09/2001

DOB: 28/06/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Bilat dorum feet.	Already and inpatient at

Medicine Details:

CEFTRIAZONE (Suspected)		Reason:	Other cellulitis and abscess
Injection	1.0 Gram	Daily	Intravenous
Batch:	Started: 11/09/2001	Stopped:	
FLAGYL (Suspected)		Reason:	Other cellulitis and abscess
Tablet	1.2 Gram	Daily	Oral
Batch:	Started: 11/09/2001	Stopped:	20/09/2001
VANCOMYCIN HYDROCHLORIDE (Suspected)		Reason:	Other cellulitis and abscess
Capsule	1.0 Gram	Daily	Oral
Batch:	Started: 11/09/2001	Stopped:	
ZOLOFT (Suspected)		Reason:	Depression
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 17/09/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergy to penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168661

Seq: 1

Gender: M

Reported: 24/09/2001

Weight: 56.00

Hospitalisation:

Age: 22

Onset Date: 19/09/2001

DOB: 28/06/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

MAGMIN (Suspected)		Reason:	
Tablet	4.0 Dose Unspecified	Daily	Oral
Batch:	Started: 17/09/2001	Stopped:	
PHOSPHATE-SANDOZ (Suspected)		Reason:	
Tablet	4.0 Dose Unspecified	Daily	Oral
Batch:	Started: 17/09/2001	Stopped:	

Laboratory Investigations:

Additional Information:

Allergy to penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168715

Seq: 1

Gender: F

Reported: 27/09/2001

Weight: 60.00

Hospitalisation:

Age: 19

Onset Date: 13/09/2001

DOB: 14/12/1981

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Headache		Occipital headaches.	
Bruxism		Teeth clenching.	Zoloft ceased after 3 doses of

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	3 times
Batch:	Started: Stopped: 17/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient commenced zoloft 25mg on 7/9/2001 for six days. reactions occurred when increased to 50mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168947 **Seq:** 1 **Gender:** M
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 69
Onset Date: 20/04/2001 **DOB:** 29/09/1931
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

Medication Details:			
LIPITOR (Other drug)		Reason:	
0.0			
Batch:	Started:	Stopped:	
NOTEN (Other drug)		Reason:	
12.5 Milligram		Daily	
Batch:	Started:	Stopped:	CONTIN
WARFARIN SODIUM (Other drug)		Reason:	
4.5 Milligram		Daily	
Batch:	Started:	Stopped:	CONTIN
ZOLOFT (Suspected)		Reason:	
50.0 Milligram		Daily	
Batch:	Started: 01/04/2001	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	ALT = SGPT AST = SGOT GGT = SGGT =				Alt - 272. Ast - 84. Ggt - 210.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168947

Seq: 1

Gender: M

Reported: 05/10/2001

Weight:

Hospitalisation:

Age: 69

Onset Date: 20/04/2001

DOB: 29/09/1931

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

OLANZAPINE (Suspected)

Reason: Unspecified psychosis

2.5 Milligram

Daily

Batch:

Started: 03/04/2001

Stopped:

CONTIN

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 168993 **Seq:** 1 **Gender:** F
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 42
Onset Date: 13/07/2001 **DOB:** 17/11/1958
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Rash			Required a visit to doctor, treated prednisolone.

Medicine Details:

PEPCIDINE (Other drug)		Reason: Other diseases of esophagus
2.0 Dose Unspecified Daily		
Batch:	Started: 01/01/1990	Stopped:
ZOLOFT (Suspected)		Reason: Depression
0.0		
Batch:	Started: 01/07/2001	Stopped: 13/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Histology				Biopsied perivascular dermatitis c/w drug reaction.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169087 **Seq:** 1 **Gender:** F
Reported: 17/10/2001 **Weight:** 84.00
Hospitalisation: Admitted to hospital **Age:** 51
Onset Date: 24/09/2001 **DOB:** 10/11/1949
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Airways decompensation.	
Urticaria	Severe	Severe allergic urticaria.	Patient was hospitalised. date of recovery: 12/10/2001.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started: 15/08/2001	Stopped: 24/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169110 **Seq:** 1 **Gender:** F
Reported: 05/10/2001 **Weight:**
Hospitalisation: **Age:** 70
Onset Date: 04/08/2001 **DOB:** 10/05/1931
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Withheld sertraline,

Medicine Details:

PANADOL (Other drug)	Reason:
0.0	As necessary
Batch:	Started: Stopped: CONTIN
RANITIDINE (Other drug)	Reason:
300.0 Milligram	Daily
Batch:	Started: Stopped: CONTIN
LIPITOR (Other drug)	Reason:
10.0 Milligram	Daily
Batch:	Started: Stopped: CONTIN
NORVASC (Other drug)	Reason: Essential benign hypertension
5.0 Milligram	Daily
Batch:	Started: Stopped: CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium	(135-144)	25/03/2001	131	
	Sodium	(135-144)	26/03/2001	135	
	Sodium	(135-144)	05/08/2001	123	
	Sodium	(135-144)	06/08/2001	128	
	Sodium	(135-144)	07/08/2001	131	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169110

Seq: 1

Gender: F

Reported: 05/10/2001

Weight:

Hospitalisation:

Age: 70

Onset Date: 04/08/2001

DOB: 10/05/1931

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

CLOPIDOGREL (Other drug)	Reason:
75.0 Milligram Daily	
Batch:	Started: Stopped: CONTIN
QUININE (Other drug)	Reason:
300.0 Milligram Daily	
Batch:	Started: Stopped: CONTIN
TEGRETOL (Suspected)	Reason:
300.0 Milligram Daily	
Batch:	Started: 01/06/2001 Stopped: 08/08/2001
ZOLOFT (Suspected)	Reason: Depression
25.0 Milligram Daily	
Batch:	Started: 03/08/2001 Stopped: 05/08/2001

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169222 **Seq:** 1 **Gender:** F
Reported: 16/10/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 72Y
Onset Date: 01/10/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Worsening depression and suicidal	Patient hospitalised

Medicine Details:

ERGOTAMINE TARTRATE (Other drug)		Reason:	Migraine
Oral application	0.0		Oral
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	Depression
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 01/09/2001	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of migraine like headaches. 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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169244 **Seq:** 1 **Gender:** M
Reported: 19/10/2001 **Weight:**
Hospitalisation: **Age:** 47Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hepatitis			
Hyponatraemia			
Suicide attempt			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	1.3 Gram	1 time	Oral
Batch:	Started:	Stopped:	
PARACETAMOL (Suspected)		Reason:	
Oral application	30.0 Dose Unspecified	1 time	Oral
Batch:	Started:	Stopped:	
MERSYNDOL (Suspected)		Reason:	
Tablet	20.0 Dose Unspecified	1 time	Oral
Batch:	Started:	Stopped:	
STILNOX (Suspected)		Reason:	
Tablet	10.0 Dose Unspecified	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169289 **Seq:** 1 **Gender:** M
Reported: 22/10/2001 **Weight:** 86.00
Hospitalisation: Admitted to hospital **Age:** 23
Onset Date: **DOB:** 25/10/1977
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hypertonia Hypertonia Palpitations Tremor Yawning		Teeth clenching.	Required a visit to doctor, patient was hospitalised. ceased zoloft

Medicine Details:

BECONASE (Other drug)	Reason: Chronic nasopharyngitis
4.0 Dose Unspecified Daily	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason: Depression
100.0 Milligram Daily	
Batch:	Started: 12/12/2000 Stopped: 10/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 20/8/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169315

Seq: 1

Gender: U

Reported: 22/10/2001

Weight:

Hospitalisation:

Age:

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169322 **Seq:** 1 **Gender:** F
Reported: 22/10/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:**
Onset Date: 28/09/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delusion Paranoia			Patient hospitalised. zoloft

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 01/09/2001	Stopped:	28/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169388 **Seq:** 1 **Gender:** F
Reported: 03/10/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 15Y
Onset Date: 17/05/1999 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient was hospitalised. date of death 22.5.1999.

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
	0.5 Dose Unspecified Daily
Batch:	Started: 14/05/1999 Stopped: 21/05/1999

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169406 **Seq:** 1 **Gender:** F
Reported: 22/10/2001 **Weight:**
Hospitalisation: **Age:** 18Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability			
Agitation			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169407

Seq: 1

Gender: M

Reported: 22/10/2001

Weight:

Hospitalisation:

Age: 55Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Affect lability			
Agitation			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169534

Seq: 1

Gender: F

Reported: 20/10/2001

Weight: 65.00

Hospitalisation:

Age:

Onset Date: 15/10/2001

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dystonia		Invuntary jaw clenching.	Required a visit to doctor. date of recovery 16.10.01.
Dysarthria			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 15/10/2001
	Stopped: 16/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Also same effect with cipramil 20mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169608

Seq: 1

Gender: F

Reported: 02/11/2001

Weight: 74.00

Hospitalisation:

Age: 31

Onset Date: 25/10/2001

DOB: 10/04/1970

Outcome: Recovered

Causality: Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Coma		Coma for 20 min.	27/10/01 - date of recovery. required a visit to doctor.
Chest pain			
Hypoaesthesia			
Nausea			
Paraesthesia			
Vomiting			

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram	Daily
Batch:	Started: 25/10/2001 Stopped: 26/10/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169690 **Seq:** 1 **Gender:** M
Reported: 01/11/2001 **Weight:**
Hospitalisation: **Age:** 66Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression			Zoloft ceased.

Medicine Details:

ARICEPT (Other drug)		Reason: Presenile dementia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169701

Seq: 1

Gender: F

Reported: 02/11/2001

Weight: 51.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 05/08/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Asthenia		Absolute exhaustion.	
Fatigue		Extreme lethargy.	
Libido decreased			Required a visit to doctor for

Medicine Details:

ZOLOFT (Suspected)	50.0 Milligram	Daily	Reason: Depression
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Suspected)	500.0 Milligram	Daily	Reason:
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169828 **Seq:** 1 **Gender:** F
Reported: 07/11/2001 **Weight:**
Hospitalisation: **Age:** 80Y
Onset Date: 16/08/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Confusional state	Required Visit to Doctor	Moderate confusion.	Stopped viox and zoloft. now on panadeine forte, panadol, pethidine and oxazepam.
Delusion	Required Visit to Doctor	Moderate delusion.	
Hallucination	Required Visit to Doctor	Moderate hallucination.	
Paranoia	Required Visit to Doctor	Moderate paranoia.	

Medicine Details:

PANAMAX (Other drug)	Reason: Osteoarthritis
Oral application	2.0 Dose Unspecified As necessary Oral
Batch:	Started: Stopped:
XALATAN (Other drug)	Reason: Unspecified glaucoma
Eye Drops	2.0 Dose Unspecified Daily Ophthalmic
Batch:	Started: L TERM Stopped:
KEFLEX (Other drug)	Reason: Otr&nos infec¶sit diseases
Oral application	3.0 Dose Unspecified Daily Oral
Batch:	Started: 15/08/2001 Stopped: 22/08/2001
VIOXX (Suspected)	Reason: Osteoarthritis
Oral application	25.0 Milligram Daily Oral
Batch:	Started: 07/08/2001 Stopped: 16/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has infection and #(l)nof.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169828

Seq: 1

Gender: F

Reported: 07/11/2001

Weight:

Hospitalisation:

Age: 80Y

Onset Date: 16/08/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 30/07/2001	Stopped: 08/08/2001	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 08/08/2001	Stopped: 16/08/2001	

Laboratory Investigations:

Additional Information:

Patient has infection and #(l)nof.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169958 **Seq:** 1 **Gender:** F
Reported: 16/11/2001 **Weight:** 92.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 27/09/2001 **DOB:** 11/08/1967
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Aggression Anxiety Psychotic disorder			Patient hospitalised. date of recovery 14/10/01.

Medicine Details:

ZOLOFT (Suspected)	Reason:	Depression
	50.0 Milligram	Daily
Batch:	Started: 26/09/2001	Stopped: 29/09/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169976 **Seq:** 1 **Gender:** M
Reported: 19/11/2001 **Weight:** 85.00
Hospitalisation: **Age:** 84
Onset Date: 05/05/2001 **DOB:** 27/12/1916
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Depression		Severe suicidal depression, life threatening	Date of recovery 12/06/01. zoloft ceased.
Suicide attempt			

Medicine Details:

Medication Details:				
ASMOL (Other drug)		Reason: Asthma		
0.0				
Batch:	Started:	L TERM	Stopped:	CONTIN
ATROVENT (Other drug)		Reason: Asthma		
0.0				
Batch:	Started:	L TERM	Stopped:	CONTIN
MONOPLUS 10/12.5 (Other drug)		Reason: Essential benign hypertension		
0.0				
Batch:	Started:		Stopped:	CONTIN
ALODORM (Other drug)		Reason:		
10.0 Milligram		Daily		
Batch:	Started:	L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Severe suicidal depression after taking first zoloft tablet 50mg. depression began within 12 hrs and continued unabated until zoloft was ceased 21 days later. took approx 3 weeks to fully recover.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 169976

Seq: 1

Gender: M

Reported: 19/11/2001

Weight: 85.00

Hospitalisation:

Age: 84

Onset Date: 05/05/2001

DOB: 27/12/1916

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

WARFARIN SODIUM (Other drug)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	21D

Laboratory Investigations:

Additional Information:

Severe suicidal depression after taking first zoloft tablet 50mg. depression began within 12 hrs and continued unabated until zoloft was ceased 21 days later. took approx 3 weeks to fully recover.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170142

Seq: 1

Gender: M

Reported: 21/11/2001

Weight:

Hospitalisation:

Age: A5

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Extrasystoles		Runs of dropped beats.	Ceased zoloft.

Medicine Details:

ZOLOFT (Suspected)	reason:	Depression
Tablet	25.0 Milligram	Daily
Batch:	Started:	Stopped:
		8D

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170145 **Seq:** 1 **Gender:** M
Reported: 21/11/2001 **Weight:**
Hospitalisation: **Age:** 77Y
Onset Date: 19/09/2001 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Ceased sertraline and started on citalapram.

Medicine Details:

IRBESARTAN (Other drug)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: CONTIN
ASPIRIN (Other drug)		Reason:	
	150.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: CONTIN
SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
	25.0 Milligram	Daily	
Batch:	Started: 01/09/2001	Stopped: 20/09/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium		18/09/2001	134	
	Sodium		21/09/2001	128	
	Sodium		01/10/2001	130	
	Sodium		13/10/2001	132	
	Sodium		16/10/2001	134	
	Sodium		23/10/2001	138	

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170287 **Seq:** 1 **Gender:** F
Reported: 26/11/2001 **Weight:**
Hospitalisation: Hospitalisation prolonged **Age:** 78Y
Onset Date: 11/08/2001 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Delirium			Patient had a prolonged stay in hospital, treated with potassium, restricted fluids. ceased indapamide, amitriptyline and sertraline.
Hyponatraemia			

Medicine Details:

ASPIRIN (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
SIMVASTATIN (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
IRBESARTAN (Other drug)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
RANITIDINE (Other drug)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	Sodium				Sodium = 125

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170287 Seq: 1

Gender: F

Reported: 26/11/2001

Weight:

Hospitalisation: Hospitalisation prolonged

Age: 78Y

Onset Date: 11/08/2001

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

VERAPAMIL HYDROCHLORIDE (Other drug)		Reason:	
Tablet	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	CONTIN
INDAPAMIDE HEMIHYDRATE (Suspected)		Reason:	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	10/08/2001
SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 28/07/2001	Stopped:	04/08/2001
AMITRIPTYLINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	2.0 Dose Unspecified	Daily	Oral
Batch:	Started: 04/08/2001	Stopped:	11/08/2001

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170412

Seq: 1

Gender: F

Reported: 29/11/2001

Weight:

Hospitalisation:

Age: 91Y

Onset Date: 08/01/2001

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Chills Cognitive disorder Tremor			Zoloft ceased. given

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression
	0.0	
Batch:	Started: 01/12/2000	Stopped: 04/01/2001
DOTHEP (Suspected)		Reason: Depression
Tablet	25.0 Milligram	As necessary Oral
Batch:	Started: 04/01/2001	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170413 **Seq:** 1 **Gender:** F
Reported: 29/11/2001 **Weight:**
Hospitalisation: **Age:** 91Y
Onset Date: 07/01/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal Tachycardia			Zoloft ceased. given aspirin

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression
	0.0	
Batch:	Started: 01/12/2000	Stopped: 04/01/2001
DOTHEP (Suspected)		Reason: Depression
Tablet	25.0 Milligram	As necessary Oral
Batch:	Started: 04/01/2001	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline,Concorz,Eleva 100,Eleva 50,GenRx Sertraline,SERTRALINE HYDROCHLORIDE,Sertraline-DP 100,Terry White Chemists Sertraline,Xydep,ZOLOFT

Report Detail

Case Number: 170559 **Seq:** 1 **Gender:** F
Reported: 29/11/2001 **Weight:** 60.00
Hospitalisation: **Age:** 88Y
Onset Date: 27/12/2000 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Flushing Chest pain Dyspepsia		Hot all over.	Stopped zoloft.

Medicine Details:

STEMETIL (Other drug)				Reason:	
Tablet	0.0	As necessary	Oral		
Batch:	Started:		Stopped:		
TEMAZEPAM (Other drug)				Reason:	
Oral application	10.0 Milligram	As necessary	Oral		
Batch:	Started:		Stopped:		
PANADEINE FORTE (Other drug)				Reason:	
Tablet	2.0 Dose Unspecified	As necessary	Oral		
Batch:	Started:		Stopped:		
ZOLOFT (Suspected)				Reason:	
Tablet	50.0 Milligram	1 time	Oral		
Batch:	Started: 27/12/2000		Stopped: 27/12/2000		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170632 **Seq:** 1 **Gender:** U
Reported: 03/12/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Overdosed on zoloft.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
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 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170811 **Seq:** 1 **Gender:** F
Reported: 03/12/2001 **Weight:** 128.00
Hospitalisation: **Age:** 28
Onset Date: 18/08/2001 **DOB:** 07/11/1972
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Skin exfoliation		Exfoliative rash on face and neck	Ceased zoloft, treated with emollient creams.

Medicine Details:

MOXACIN (Other drug)	Reason: Otr&nos infec¶sit diseases
1.5 Gram Daily	
Batch:	Started: 31/07/2001 Stopped:
ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 31/07/2001 Stopped: 20/08/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 28/8/01.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 170833 **Seq:** 1 **Gender:** M
Reported: 03/12/2001 **Weight:** 72.00
Hospitalisation: **Age:** 34
Onset Date: 13/11/2001 **DOB:** 12/11/1967
Outcome: Unknown **Causality:** Causality probable

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome Nervousness Paraesthesia		Lightheadedness especially when turning	Sertraline ceased over one week, slowly, still had symptoms for 2 weeks later took single 50 mg tab sertraline resolved.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
25.0 Milligram Daily	
Batch:	Started: L TERM Stopped:
SODIUM VALPROATE (Other drug)	Reason:
1.0 Gram Daily	
Batch:	Started: L TERM Stopped:
SERTRALINE HYDROCHLORIDE (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 01/07/2001 Stopped: 13/11/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 171015 **Seq:** 1 **Gender:** M
Reported: 13/12/2001 **Weight:**
Hospitalisation: Admitted to hospital **Age:** 81
Onset Date: 10/12/2001 **DOB:** 18/09/1920
Outcome: Recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			Vit k, ffp, rbc transfusion. patient hospitalised. date of recovery 11/12/01.

Medicine Details:

WARFARIN SODIUM (Interaction)	Reason:
3.0 Milligram	Daily
Batch:	Started: Stopped:
ZOLOFT (Interaction)	Reason:
100.0 Milligram	Daily
Batch:	Started: Stopped:
LANOXIN PG (Other drug)	Reason:
2.0 Dose Unspecified	Daily
Batch:	Started: Stopped:
EPILIM (Other drug)	Reason:
1.0 Gram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
	International		10/12/2001	>10	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 171015 Seq: 1

Gender: M

Reported: 13/12/2001

Weight:

Hospitalisation: Admitted to hospital

Age: 81

Onset Date: 10/12/2001

DOB: 18/09/1920

Outcome: Recovered

Causality: Causality possible

Reaction Detail

Medicine Details:

TEMAZE (Other drug)	Reason:
10.0 Milligram Daily	
Batch:	Started: Stopped:
EXELON (Other drug)	Reason:
3.0 Milligram Daily	
Batch:	Started: Stopped:
DITROPAN (Other drug)	Reason:
10.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 171138 **Seq:** 1 **Gender:** M
Reported: 17/12/2001 **Weight:**
Hospitalisation: **Age:** 48Y
Onset Date: 28/05/2001 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Erectile dysfunction	Medication changed to
Libido decreased		Loss of libido.	

Medicine Details:

ZOLOFT (Suspected)	Reason: Depression
50.0 Milligram Daily	
Batch:	Started: 01/01/1996 Stopped: 28/05/2001
ZOLOFT (Suspected)	Reason: Depression
150.0 Milligram Daily	
Batch:	Started: 28/05/2001 Stopped: CONTIN
TRAMAL (Suspected)	Reason:
100.0 Milligram Daily	
Batch:	Started: 01/03/2001 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 may 2001. zoloft was commenced sometime in 1996 and the dose was 50 - 150 mg per day. this was continued till sometime in may 2001. the dose was then increased to 150 - 250 mg daily. the dose start date for tramal is also not necessarily accurate but indicates it was begun sometime in march 2001.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Detail

Case Number: 172009 **Seq:** 1 **Gender:** F
Reported: 03/12/2001 **Weight:**
Hospitalisation: **Age:**
Onset Date: 03/04/2000 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Detail

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities			
Neonatal disorder			

Medicine Details:

SODIUM VALPROATE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
CARBAMAZEPINE (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
AROPAX (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:
ZOLOFT (Suspected)	Reason:
0.0	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Little boy was born 3/4/00. mother took sodium valproate from the time of conception until delivery at term. at 11 months old he had dysmorphic facial features (mild hypotelorism, epicanthic folds, infra-orbital ridging, upslanting palpable fissures, flat nasal bridge, anteverted nares, smooth philtrum, slightly thin upper lip) and metopic + right lamoidal craniosynostosis leading to trigonencephaly and asymmetrical brachycephaly. at this time his development was within the normal range.