

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Mania			Zoloft dose reduced to

Medicine Details:

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

3atch: Started: Stopped:

Laboratory Investigations:

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

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 Detai

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

Medicine Details:

Medicine Details.			
ZOLOFT (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily Oral	
3atch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	10.0 Milligram	Daily	
3atch:	Started:	Stopped:	

Laboratory Investigations:

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

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 Detai

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

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/01/1999
 3topped:
 28/12/1999

Laboratory Investigations:

Date	Туре	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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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 Detai

Preferred Term	Severity	Report Description	Treatment
Epistaxis			

Medicine Details:

DOXYCYCLINE HYDROCHLORIDE (S	Suspected)	Reason:	
	200.0 Milligram	Daily	
Зatch:	Started: 10/12/1999	Stopped:	17/12/1999
ZOLOFT (Suspected)		Reason:	

Tablet 200.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



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

Report Detail

 Case Number:
 147841
 Seq: 1
 Gender: M

 Reported:
 10/01/2000
 Weight:

Hospitalisation:
Onset Date: 31/12/1999
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

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

Report Deta	ı	ı
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Rectal haemorrhage			

Medicine Details:

ZOLOFT (Suspected) Reason: Obsessive compulsive neurosis

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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 D)etail
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 Case Number:
 147909
 Seq: 1
 Gender: F

 Reported:
 12/01/2000
 Weight:

Hospitalisation: Age: 41Y

Onset Date: 17/07/1999

Outcome: Recovered

Causality: Causality probable

Reaction Detai

todotion Dotal			<u> </u>
Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Severe diarrhoea	Given salazopine.
Colitis			

Medicine Details:

MINULET (Other drug) Reason: Contraception

1.0 Dose Unspecified Daily

3atch: Started: Stopped:

ZOLOFT (Suspected) Reason:

50.0 Milligram Daily

3atch: 3tarted: 10/06/1999 3topped:

Laboratory Investigations:

	J						
Date	Туре	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 Detai

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

3atch: 3tarted: 05/01/2000 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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

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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason:

100.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

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

Report Detail

 Case Number:
 148028
 Seq: 1
 Gender:
 F

 Reported:
 18/01/2000
 Weight:
 54.00

 Hospitalisation:
 Age: 34Y

Onset Date: 23/11/1999

Outcome: Not yet recovered

Causality: Causality possible

Reaction Detai

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

Medicine Details:

HALDOL DECANOATE (Suspected)		Reason:	
	25.0 Milligram	Fortnightly	
3atch:	3tarted: 30/10/1999	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspec	ted)	Reason: Depression	
Tablet	150.0 Milligram	Daily	Oral
Batch:	3tarted: 23/11/1999	Stopped:	26/11/1999
LITHIUM CARBONATE (Suspected)		Reason: Depression	
LITHIUM CARBONATE (Suspected)	530.0 Milligram	Reason: Depression Daily	
LITHIUM CARBONATE (Suspected) 3atch:	530.0 Milligram 3tarted: 12/11/1999	·	25/11/1999
	· ·	Daily	25/11/1999
3atch:	· ·	Daily Stopped:	25/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	148028	Seq:	1		Gender:	F
Reported:	18/01/2000				Weight:	54.00
Hospitalisation:					Age:	
Onset Date:	23/11/1999				DOB:	
Outcome:	Not yet recovered				Causality:	Causality possible
Reaction Detai						
Medicine Deta	aile:					
NICOTINE TRANS	DERMAL PATCH (Sus	pected	I)	Reason:		
Cream			10.0 Milligram	Daily	Transderm	al
3atch:		Sta	rted: 03/11/1999		Stopped:	
Laboratory In	vestigations:					
	and a second second					
Additional Inf	ormation:					
Additional iiii	offication.					



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

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 Detai

Preferred Term	Severity	Report Description	Treatment
Extrasystoles			
Palpitations			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 01/01/1999 3topped: 31/01/1999

Laboratory Investigations:

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

Report Detail				
Case Number: 148171 Reported: 17/01/2000 ospitalisation:	Seq: 1			nder: F eight: Age: 70Y
Onset Date: Outcome: Recovered				DOB: sality: Causality possible
eaction Detai			Oaus	daily. Causality possible
Preferred Term	Severity	Repor	t Description	Treatment
Pizziness	- Covering	1.0001	t Bootinption	riodinone
lausea				Zoloft ceased.
ledicine Details: ZOLOFT (Suspected)		Reas	on: Depression	
Tablet	50.0 M		Daily Ora	al
3atch:	Started:	ŭ	Stopped:	1W
aboratory Investigation	s:			
	Range Date Tested	d Result		Details
dditional Information:				
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

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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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Ceased sertraline

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

0.0

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report D	etail							
Case Num	nber:	148236	Seq:	1		(Gender:	F
Repo	rted:	20/01/200	0			,	Weight:	
Hospitalisa							Age:	
		10/01/200					DOB:	
		Recovere	d			Ca	usality:	Causality possible
Reaction E			i .	1			i	
-	eferre	d Term	Seve			Description		Treatment
Rash				Joeve	or chacerball	on of generalised	ji icc	Inisolone
Medicine								
ZOLOFT (Su	uspect	ed)			Reas	•		
			_	50.0 Mill		Daily		
3atc	:h:		3ta	rted: 03/01/2	000	Stopped:	10/01/2000)
Laborato	ry In	vestigat	ions:					
Date		Туре	Range	Date Tested	Result		Deta	ils
۸ ما ما ن د : م به م	ما اما	iormatia	n.					
Additiona	aı ını	ormatio	II.					



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

Report Detail

 Case Number:
 148273
 Seq: 1
 Gender: U

 Reported:
 24/01/2000
 Weight:

Hospitalisation:
Onset Date: 31/12/1999
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			Zoloft ceased.
Tremor			

Medicine Details:

ZOLOFT (Suspected) Reason: Unspecified psychosis

50.0 Milligram Daily

3atch: 3tarted: 01/11/1998 **3topped:** 28/11/1998

Laboratory Investigations:

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

Report Detail

 Case Number:
 148274
 Seq: 1
 Gender: F

 Reported:
 24/01/2000
 Weight:

Hospitalisation:
Onset Date: 31/12/1999
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dizziness			Zoloft reduced

Medicine Details:

Medicine Details.			
RISPERDAL (Suspected)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
	50.0 Milligram	Daily	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report De	etail
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Onset Date: 31/01/2000 **DOB:**

Outcome: Unknown

Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Anxiety			
Insomnia			

Medicine Details:

ZOLOFT (Suspected) Reason: Obsessive compulsive neurosis

12.5 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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 Detai

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

3atch: Started: Stopped:

Laboratory Investigations:

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

Report De	etail					
Report Hospitalisati		Seq:	1			iender: M Veight: Age: 38Y
Onset D	ate: me: Unknown				Cai	DOB: usality: Causality possible
Reaction D					Cat	Jeanty. Causanty possible
	ferred Term	Seve	rity	Repor	Description	Treatment
Agitation						Zoloft reduced to 50mg/day.
Medicine ZOLOFT (Sus				Reas	on: Depression	
	,		100.0 Milli		Daily	
3atch	ı:	Star	arted:		Stopped:	3W
	y Investigat					
Laborator Date	r y Investigat Type		Date Tested	Result		Details



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

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 Detai

todotion Dotai		<u> </u>	
Preferred Term	Severity	Report Description	Treatment
Mania		Hypomania	
Agitation			
Neurosis			It is planned to reduce the dose of zoloft.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

200.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Ceased zoloft.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: Started: Stopped: 4W

Laboratory Investigations:

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

Rep	ort	Detail
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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 Detai

teaction Detai			
Preferred Term	Severity	Report Description	Treatment
Depression			
Drug ineffective			
Suicide attempt			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

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

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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: Started: 01/01/1998 **Stopped:** 20/08/1999

PSEUDOEPHEDRINE NOS (Suspected) Reason: Ac upr resp inf,mult,unsp stes

360.0 Milligram Daily

3atch: 3tarted: 17/08/1999 3topped: 20/08/1999

Laboratory Investigations:

Date	Туре	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.



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

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 Detai

Preferred Term	Severity	Report Description	Treatment
Hepatitis cholestatic			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 01/10/1999 3topped: 28/12/1999

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 01/05/1998 3topped: 10/01/2000

Laboratory Investigations:

Date	Туре	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.

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

Rep	ort	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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 01/05/1998 3topped: 10/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Intial 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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 300.0 Milligram
 Daily
 Oral

 3atch:
 Started:
 01/10/1999
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Interaction)			Reason:	Depression
	50.0	Milligram	Daily	
3atch:	Started:			Stopped:
DOXEPIN HYDROCHLORIDE (Interaction)			Reason:	Otr&unsp vertebrogen pain synd
	10.0	Milligram	Daily	

3atch: Started: Stopped:

Laboratory Investigations:

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

 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 Detai

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

 3atch:
 Started:
 14/01/2000
 Stopped:
 25/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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		Ge	ender: F		
Reported: 31/01/2000			W	eight:		
Hospitalisation:				Age: 40Y		
Onset Date: 25/01/2000)			DOB:		
Outcome: Unknown			Caus	sality: Causality possible		
Reaction Detai				•		
Preferred Term	Severity	Repor	Description	Treatment		
Anxiety						
Dizziness				Zoloft ceased.		
Medicine Details: ZOLOFT (Suspected) Season: Depression 50.0 Milligram Daily 3atch: Started: 15/01/2000 Stopped: 25/01/2000						
Laboratory Investigation	O ns: Range Date Te	sted Result		Details		
	L					
Additional Information	:					



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Anaemia			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

0.0

3atch: **Started**: 01/01/1998 **Stopped**:

Laboratory Investigations:

Date	Туре	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.

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

 Case Number:
 148451
 Seq: 1
 Gender:
 F

 Reported:
 31/01/2000
 Weight:

Hospitalisation: Age: 58Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Anxiety			

Medicine Details:

ZOLOFT (Suspected)Reason:DepressionTablet50.0 MilligramDailyOral

3atch: Started: Stopped: 1W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pt also taking rocaltrol and diazepam.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Reported: 01/02/2000 Hospitalisation: Onset Date: Outcome: Unknown	Seq: 1	Gender: F Weight: 73.00 Age: AD DOB: Causality: Causality possil		
eaction Detai Preferred Term	Severity	Report Descriptio	n Treatment	
Drug ineffective				
Medicine Details: SERTRALINE HYDROCHLORIDE Tablet 3atch:	(Suspected) 200.0 Milli Started:		ssion Oral pped: 09/12/1999	
Laboratory Investigatio	ne:			
Date Type	Range Date Tested	Result	Details	
Additional Information:				



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100000000000000000000000000000000000000			
Preferred Term	n Severity	Report Description	Treatment
Mania		Hypomanic reaction	Ceased sertraline. given lithiun carbonate 500mg bd.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

300.0 Milligram Daily

3atch: 3tarted: 01/09/1999 3topped: 28/11/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 24/12/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Severity	Report Description	Treatment
		Discontinue sertraline and substitute with moclobemide. previous supplemented na+ via
	Severity	

Medicine Details:

 SERTRALINE HYDROCHLORIDE (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/12/1999
 3topped:
 30/12/1999

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 24/12/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

3atch: **3tarted**: 01/12/1999 **3topped**: 30/12/1999

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 24/12/1999
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

3atch: Started: 01/12/1999 Stopped: 30/12/1999

Laboratory Investigations:

Date	Туре	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.

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

 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 Detai

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

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 100.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 05/01/1998
 \$topped:
 17/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



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

Report	Detail
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Case Number: 149162 Seq: 1 Gender: F
Reported: 16/02/2000 Weight:
Hospitalisation: Age: 34Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

200.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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 neurologial review, it was considered the eeg findings were consistent with a post-ictal disturance, rather than the development of epilepsy per se.		

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 04/02/2000 3topped: 10/02/2000

Laboratory Investigations:

Date	Туре	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.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 149175	Seq: 1			Gender: F		
Reported: 16/02/2000	•		Weight:			
lospitalisation:				Age : 10Y		
Onset Date:				DOB:		
Outcome: Recovered			Ca	Causality: Causality probable		
eaction Detai						
Preferred Term	Severity	Report	Description	Treatment		
Aggression				Zoloft discontinued.		
Insomnia						
Mania						
Medicine Details: ZOLOFT (Suspected)		Reaso	n: Obsessive com	npulsive neurosis		
Tablet	12.5 M			Oral		
3atch:	Started:	g.a	Stopped:	o.u.		
_aboratory Investigatio	ns: Range Date Teste	d Result		Details		
Туре	Trange Date rester	d Result		Details		
Additional Information:						



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

Report	t Detail
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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 Detai

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Cerebral haemorrhage			
Syncope			

Medicine Details:

ZOLOFT (Interaction)		Reason:		
Tablet	0.0	Daily	Oral	
Batch:	Started:	Stop	oed:	
WARFARIN SODIUM (Interaction)		Reason:		
Tablet	0.0	Daily	Oral	
			ped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

This event occurred 3 to 4 years ago.



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

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

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

300.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report De								
Case Numb	er: 149182	Seq:	1	Gender: M				
Report	ed: 16/02/2000				Weight:			
ospitalisati	on:					Age: 63Y		
Onset Da	ate:			DOB:				
Outcor	ne: Not yet reco	overed		Causality: Causality possible				
eaction De	etai							
Pref	erred Term	Sev	erity	Report D	escription	Treatment		
Dysuria								
Nephrolithias	sis							
Jrinary tract	infection							
ZOLOFT (Sus	pected)			Reason:				
ZOLOFT (Sus Table	pected) t		0.0	Reason:		Oral		
ZOLOFT (Sus	pected) t	Sta	0.0 arted:	Reason:	C Stopped:	Oral		
Tablei 3atch :	pected) t :			Reason:		Oral		
ZOLOFT (Sus Tablet 3atch:	pected) t			Result		Dral Details		

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction			Zoloft was discontinued

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zoloft was discontinued and changed to another anitidepressant, 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.

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

Report D)etail
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 Case Number:
 149188
 Seq:
 1
 Gender:
 F

 Reported:
 16/02/2000
 Weight:
 Weight:

Hospitalisation: Age: 52Y

Onset Date: 31/12/1999 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Nausea		Severe nausea	Ceased zoloft

Medicine Details:

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

Laboratory Investigations:

Date	Туре	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.

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

	Re	oa	rt	D	eta	i	ı
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Case Number: 149191 Seq: 1 Gender: F
Reported: 16/02/2000 Weight:
Hospitalisation: Age: 35Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dystonia		Lockjaw	Ceased zoloft.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

0.0 Milligram 5 times

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient previously expereinced same symptoms while on amitriptyline.



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

Report Detail	Re	ро	rt C	Deta	il
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Case Number: 149192 Seq: 1 Gender: F
Reported: 16/02/2000 Weight:

Hospitalisation: Age: 30Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			Ceased zoloft

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

600.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
Onset Date: 31/01/2000
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 100.0
 Milligram
 Daily
 Oral

 3atch:
 Started:
 01/11/1999
 Stopped:
 28/01/2000

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Pruritus		ltch all body.	
Drug withdrawal syndrome			
Insomnia			
Nausea			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 01/11/1999 3topped: 28/01/2000

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal			
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

3atch: **Started**: 01/01/1999 **Stopped**:

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

Medicine Details.		
KEFLEX (Suspected)	Reason:	
Oral application	3.0 Dose Unspecified Daily	Oral
3atch:	Started: 02/02/2000	Stopped: 09/02/2000
ZOLOFT (Suspected)	Reason:	
Tablet	1.0 Dose Unspecified Daily	Oral
3atch:	Started: 02/02/2000	Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking aropax, temaze, aureomycin oint.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected)

Tablet

100.0 Milligram

Daily

Oral

Started:

Stopped: 8M

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

Tablet 150.0 Milligram Daily Oral

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	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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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: Started: L TERM Stopped: 16/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 149921	Seq: 1			ender: M
Reported: 03/03/2000			V	Veight: 130.00
ospitalisation:				Age: 60Y
Onset Date:				DOB:
Outcome: Recovered			Cau	isality: Causality probable
eaction Detai				
Preferred Term	Severity	Report De	escription	Treatment
Hyperhidrosis				
Mania				
Salivary hypersecretion				Zoloft discontinued and the patient was started on
Medicine Details:			Danmasian	
ZOLOFT (Suspected)	200.0 Mi	Reason:	Depression	
3atch:	3tarted:	illigram Da S TERM	ny Stopped:	
aboratory Investigations				
Date Type F	Range Date Tested	Result		Details
Additional Information:				



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 24/02/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 1.0 Dose Unspecified Daily Oral

3atch: **3tarted**: 24/02/2000 **3topped**: 24/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had been hyperventilating. fingers became contorted.



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

Report Detail	Re	ро	rt C	Deta	il
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Imodium
Rash erythematous			

Medicine Details:

Medicine Details.			
ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
3atch:	3tarted: 02/11/1999	Stopped	: 16/02/2000
STELAZINE (Suspected)		Reason: Depression	
	2.0 Milligram	Daily	
3atch:	Started: 26/11/1999	Stopped	: 09/02/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



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

Report D)etail
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Case Number: 149975 Seq: 1 Gender: F
Reported: 03/03/2000 Weight:
Hospitalisation: Age: A3
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion botal			
Preferred Term	Severity	Report Description	Treatment
Dizziness			
Nausea			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms each time zoloft dose was increased.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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		Gend	ler: F
Reported: 03/03/2000			Weig	jht:
Hospitalisation:			A	ge:
Onset Date:			D	OB:
Outcome: Unknown			Causal	ity: Causality possible
Reaction Detai	1			
Preferred Term	Severity		t Description	Treatment
Weight increased		Weight gain of 10	kg.	
Medicine Details: ZOLOFT (Suspected)	100.0	₹eas Milligram	on: Depression Daily	
3atch:	Started:	3	Stopped:	
Laboratory Investigatio	ns:			
Date Type	Range Date Te	ested Result		Details
Additional Information:				



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Reported: 03/03/2000 ospitalisation: Onset Date: Outcome: Unknown	Seq: 1	\	Gender: U Weight: Age: DOB: usality: Causality possible
eaction Detai	0	December 1997	Transferred
Preferred Term Hyperhidrosis	Severity	Report Description essive sweating	Treatment
ledicine Details: ZOLOFT (Suspected)		Reason: Depression	
3atch:	100.0 Milli 3tarted:	igram Daily 3topped:	
aboratory Investigatio	one:		
_aboratory Investigatio	Dns: Range Date Tested	Result	Details



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

Report Do	etail
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 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 Detai

Preferred Term	Severity	Report Description	Treatment
Insomnia			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

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

7	44:1					
Repor Ospitalisat Onset D	ber: 149980 ted: 03/03/200		1		Weiç A Dû	der: M ght: .ge: 48Y OB: lity: Causality possible
action D		u			Gausai	ity. Causanty possible
	eferred Term	Sev	erity	Report Des	cription	Treatment
jaculation	failure					Zolft was discontinued.
	Details:			2000001	Donrossian	
OLOFT (Su Tabl			25.0 Milliç	Reason: gram Daily	Depression Oral	
3atcl		Sta	ırted:	gram Dany	Stopped:	2W
aborato i _{Date}	r y Investigat	ions:	Date Tested	Result		Details
I aborato	rv Investigat	ions:				



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

touction Botal			
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	
ZOLOFT (Suspected) Tablet	50.0 Milligram	Reason: Daily	Depression Oral	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

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

Case Number: 149986	Seq: 1		Gen	der: F
Reported: 03/03/2000	-		Wei	ght:
ospitalisation:				\ge : 18Y
Onset Date:			D	OB:
Outcome: Recovered			Causa	llity: Causality possible
eaction Detai				
Preferred Term	Severity	Repor	t Description	Treatment
Agitation		Severe agitation		Patient was commenced on 100mg/day dose of zoloft and experienced symptoms, dose of zoloft was reuced to 50mg/day, was later increased to 75mg/day without problems.
Anxiety		Severe anxiety.		
Medicine Details: ZOLOFT (Suspected)		Reas	on: Depression	
	100.0) Milligram	Daily	
3atch:	Started:		Stopped:	
Laboratory Investigation Date Type		poted Decult		Details
Date Type	Range Date To	ested Result		Details
Additional Information:				
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 01/01/1998 3topped: 17/02/2000

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: 3tarted: 15/02/2000 3topped: 24/02/2000

Laboratory Investigations:

Date	Туре	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.

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

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Case Number: 150133 Seq: 1 Gender: M
Reported: 09/03/2000 Weight:
Hospitalisation: Age: 36Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase incr			

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression
Tablet	200.0 Milligram	Daily	0
3atch:	Started:		Stopped:

Laboratory Investigations:

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

Additional Information:



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

Report Do	etail
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Case Number: 150134 Seq: 1 Gender: F
Reported: 09/03/2000 Weight:
Hospitalisation: Age: 80Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
		. пореже денем	
Hypokalaemia			
Hyponatraemia			
Nausea			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Report Detail									
Case Number:	150136	Seq:	1			Gend	ler: F		
Reported: 09/03/2000			·			Weight:			
spitalisation: /	Admitted to h	ospital				Α	ge: 59Y		
Onset Date:						DO	OB:		
Outcome:	Recovered					Causal	ity: Causality probable		
action Detai			1			<u> </u>			
Preferred	Term	Seve	erity	Repo	rt Descriptior	1	Treatment		
izziness									
eadache	_						Zoloft ceased		
rthostatic hypote omiting	ension								
ledicine Deta				202	son: Depres	sion			
Tablet	4)		50.0 Millig		Daily	Oral			
3atch:		Sta	rted:	j. u	-	ped:	1W		
aboratory Inv	vestigation	ns:							
	Туре	Range	Date Tested	Result			Details		
dditional Info	ormation:								
oort Run 27/07/200	03:25PN I	Database: pu	sime		ADRS004		Page 73 of 591		



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

Report Detail	Re	po	rt	D	eta	i
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Gout			

Medicine Details:

ZOLOFT (Suspected) Reason:

0.0

3atch: 3tarted: 14/11/1999 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report Detail	Re	po	rt	D	eta	i
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Case Number: 150194 Seq: 1 Gender: F
Reported: 09/03/2000 Weight:
Hospitalisation: Age: 44Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

<u></u>			
ZOLOFT (Suspected)		Reason:	
Tablet	0.0	Oral	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking hormone replacement therapy - not specified.



Reported: 09/03/2000 pspitalisation: Onset Date: Outcome: Recovered action Detai	Seq: 1	Gender: F Weight: Age: 53Y DOB: Causality: Causality possible
Preferred Term	Severity	Report Description Treatment
atigue izziness lausea	F	Patient complained of tiredness and feeling Zoloft ceased. Patient felt dizzy. Patient felt nauseous.
adiaina Datallas		
		Reason: Unspecified schizophrenia
STELAZINE (Other drug)	0.0	
STELAZINE (Other drug) Batch:	0.0 Started:	Stopped:
STELAZINE (Other drug) 3atch: ZOLOFT (Suspected)	Started:	Stopped: Reason: Depression
		Stopped:
STELAZINE (Other drug)	Started:	Stopped:
STELAZINE (Other drug) 3atch: ZOLOFT (Suspected) Tablet	Started: 50.0 Started:	Stopped: Reason: Depression Milligram Daily Oral Stopped:



Report De					
Case Num Repor Hospitalisat	ber: 150198 ted: 09/03/2000	Seq: 1		_	t: e: 83Y
Onset D				DOE	
Outco Reaction D	ome: Recovered			Causality	: Causality possible
	eferred Term	Severity	Report Description		Treatment
Diarrhoea		Severe	Patient experienced severe diarrhoo	ea. Zo we	loft ceased after three eks therapy.
Medicine					
ZOLOFT (Su		50	Reason: Depression O Milligram Daily	Oral	
3atcl		Started:	o willigram Dally		3W
	ry Investigati		Tarket I. Davit I	200	
Laborato Date	ry Investigati Type	O ns: Range Date T	rested Result	De	tails



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 Started:
 S TERM
 Stopped:
 CONTIN

Laboratory Investigations:

Date	Туре	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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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

3atch: Started: STERM Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has been taking zoloft for 1 month.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:

Reported: 09/03/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOLOFT (Suspected)

Tablet

100.0 Milligram

Daily

Oral

3atch: STERM

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has been on zoloft for approximately three months.



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

Rep	ort	Detail
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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 Detai

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			None.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: Started: STERM Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has been on zoloft for 12 months.



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

Report D)etail
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Case Number: 150205 Seq: 1 Gender: F
Reported: 09/03/2000 Weight:
Hospitalisation: Age: 65Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

104011011 20141			
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

3atch: Started: Stopped: 5D

Laboratory Investigations:

Date	Туре	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.



Report De							
	etail						
Case Num	ber: 150206	Seq: 1		Gende	r: F		
Repor	ted: 09/03/2000)		Weight:			
Hospitalisat	tion:			Age	e: A2		
Onset D				DO			
	me: Not yet rec	overed		Causalit	y: Causality possible		
eaction D			 				
	eferred Term	Severity	Report Des		Treatment		
Anxiety			Patient has experienced	-	one.		
Palpitations			Patient has experienced	d palpitations.			
Medicine			2				
ZOLOFT (Su Table		100.0	Reason: Milligram Daily	Oral			
3atcl		Started:	Willingram Daily	Stopped:	CONTIN		
Laborato	ry Investigatio		ested Result	De	otails		
	ry Investigation		ested Result	De	etails		



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

Report Detail	Re	ро	rt C	Deta	il
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 Case Number:
 150207
 Seq: 1
 Gender:
 F

 Reported:
 09/03/2000
 Weight:

Hospitalisation:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOLOFT (Suspected)

Tablet 50.0 Milligram Daily Oral

3atch: Started: S TERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient on zoloft for 10 days.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression		
Tablet	200.0 Milligram	Daily		Oral	
3atch:	Started:		Stopped:		6W

Laboratory Investigations:

Date	Туре	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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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression	
Tablet	100.0 Millig	am Daily	,	Oral
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Dotai		_	
Preferred Term	Severity	Report Description	Treatment
Rash			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

3atch:

\$topped: 1W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Detail				
Case Number: 150212 Reported: 09/03/2000 ospitalisation:	Seq: 1		Wei	der: F ght: Age: 65Y
Onset Date: 01/02/2000			D	OB:
Outcome: Recovered			Causa	lity: Causality probable
eaction Detai				
Preferred Term	Severity	Report	Description	Treatment
atigue			d excessive lethargy.	
Somnolence	F	Patient experience	d excessive sleepiness.	Zoloft ceased.
Medicine Details:				
ZOLOFT (Suspected)		Reaso	n: Depression	
Tablet	25.0	Milligram	Daily Oral	
3atch:	Started:	Ü	Stopped:	3D
Laboratory Investigation	1S: Range Date Tes	ted Result		Details
Additional Information:				



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Dotai		_	
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

 3atch:
 Started:
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has a history of suicidal inclinations.



	d : 09/03/2000	Seq:				Weight:	
spitalisatio						Age: DOB:	
Onset Dat	e: Recovered						Causality possible
action De						oausanty.	Causanty possible
	rred Term	Seve	rity	Report	Description		Treatment
ghtmare					•		
edicine D				Reaso	n: Anxiety neur	osis	
Tablet	colou,		50.0 Milli		Daily	Oral	
3atch:		3tar	ted:				
	Investigatio		Date Tested	Recult		Deta	ile
aboratory Date	Investigatio Type		Date Tested	Result		Deta	ils



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

104011011 20141			=
Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			None.
Hyperprolactinaemia			

Medicine Details:

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

3atch: 3tarted: 01/10/1999 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Caction Betai		_	
Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Patient developed withdrawal syndrome.	Reinitiation of zoloft 50mg
Malaise		Patient feeling unwell.	1
Headache			
Tremor			

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started: 01/08/1998

Stopped:

Laboratory Investigations:

Date	Туре	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.

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tail							
er: 150217	Seq:	1		G	ender: F		
Reported: 09/03/2000			Weight:				
on:					Age: 40Y		
ate:					DOB:		
	d			Cau	sality: Causality possible		
etai					<u> </u>		
erred Term	Seve	rity	Report	Description	Treatment		
Details: pected)		50.0 Milli			oral		
:	Star	ted:		Stopped:			
y Investigat		Data Tastad	- Pocult		Dotails		
y Investigat ^{Type}	ions: Range	Date Tested	Result		Details		
	per: 150217 ped: 09/03/200 pon: petai perred Term Details: pected)	per: 150217 Seq: ed: 09/03/2000 con: ete: me: Recovered etai erred Term Seve	per: 150217 Seq: 1 ed: 09/03/2000 pon: ete: me: Recovered etai erred Term Severity Details: pected) 50.0 Milli	per: 150217 Seq: 1 ed: 09/03/2000 con: ete: me: Recovered etai erred Term Severity Report Details: pected) Reaso 50.0 Milligram	per: 150217 Seq: 1 G ed: 09/03/2000 V con: tote: ne: Recovered Cau etai erred Term Severity Report Description Details: pected) Reason: Depression 50.0 Milligram Daily C		



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

Report D)etail
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

ZOLOFT (Suspected) Reason:

100.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 3topped: 18/02/2000 2W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 05/03/2000 **3topped:** 08/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Biliary colic			
Hepatic function abnormal			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 11/05/1999 3topped: 25/02/2000

Laboratory Investigations:

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

Additional Information:

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

Report Detail

Case Number:150540Seq:1Gender:FReported:21/03/2000Weight:Hospitalisation:Admitted to hospitalAge:48Y

Onset Date: 31/12/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Nausea	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	
3atch:	Started:	Stopped:	3D
AURORIX (Interaction)		Reason: Depression	
	600.0 Milligram	Daily	
I	Started:	Stopped:	2W

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal		E	
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

 3atch:
 3tarted:
 01/02/1999
 3topped:
 28/03/1999

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

 3atch:
 Started:
 Stopped:
 3M

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had no history of epilepsy.



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

Report Detail

Case Number:150617Seq: 1Gender:FReported:21/03/2000Weight:Hospitalisation:Age: A3

Onset Date: 31/01/2000 DOB:
Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence			Imipramine

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report D)etail
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Case Number:150619Seq:1Gender:FReported:21/03/2000Weight:Hospitalisation:Admitted to hospitalAge:55Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detail

10404011 20141			
Preferred Term	Severity	Report Description	Treatment
Agitation			Zoloft ceased
Agitation			
Anxiety			
Insomnia			

Medicine Details:

ZOLOFT (Suspected) Reason: Anxiety neurosis

25.0 Milligram Daily

3atch: Started: Stopped: 3D

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Loperamide and metronidazole

Medicine Details:

ZOLOFT (Suspected) Reason:

50.0 Milligram Daily

3atch: 3tarted: 01/01/2000 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Deta							
	ıil						
Case Numbe	r: 150621	Seq: 1		Gende	er: F		
Reported	d: 21/03/200	-		Weigh	nt:		
Hospitalisation	ո։			Ag	e: 22Y		
Onset Date	e: 25/02/200	0		DO	B:		
Outcome	e: Recovered	İ		Causalit	y: Causality probable		
Reaction Det	ai			<u> </u>			
Prefer	red Term	Severity	Report	Description	Treatment		
Anxiety			Exacerbate the pa	tient anxiety			
Conversion dis				Z	oloft ceased		
Drug ineffective	e						
Madiaina D	oto:lo:						
Medicine De			2025	on: Anxiety neurosis			
ZOLOFT (Suspe	cteu)	100 (Reason: Anxiety neurosis 100.0 Milligram Daily				
3atch:			Started: 20/02/2000 Stopped: 25/02/2000				
Labaustaus	1						
Laboratory Date			ested Result	D	etails		
	Type		ested Result	D	etails		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

F	Reaction Detai			
	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

3atch: 3tarted: 01/11/1999 3topped: 28/03/2000

Laboratory Investigations:

Date	Туре	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.



Report Detail			
Case Number: 150623	Seq: 1	Gende	er: F
Reported: 21/03/2000		Weig	
Hospitalisation:			je: 39Y
Onset Date:	_	DO	
Outcome: Not yet recov	vered	Causali	ty: Causality possible
Preferred Term	Severity	Report Description	Treatment
Hyperkinesia		uding teeth gnashing and leg jerking at	rreatment
Medicine Details: ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Mil		
3atch:	Started:	Stopped:	CONTIN
Laboratory Investigation			
Laboratory Investigation Date Type	ns: Range Date Tested	Result D	etails



Report Detail				
Case Number: 150625 Reported: 21/03/2000 Hospitalisation: Onset Date: Outcome: Recovered Reaction Detai	Seq: 1		der: F ght: ge: 20Y OB: lity: Causality possible	
Preferred Term	Severity	Report	Description	Treatment
Syncope				Zoloft ceased
Medicine Details: ZOLOFT (Suspected) Tablet 3atch:	50.0 Started:	Reaso Milligram	on: Depression Daily Oral Stopped:	
Laboratory Investigatio	ine:			
Date Type	Range Date Te	ested Result		Details
Additional Information:				



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 150627		Seq:	1		Gender: F				
	ted: 21/03/2000	_					Weight:		
ospitalisat	ion:						Age:	48Y	
Onset D	ate:						DOB:		
Outcome: Unknown						С	ausality:	Causality poss	sible
eaction D			1						
	eferred Term	Sev	erity	Repo	t Descr	ription		Treatment	t
Anorgasmia									
ibido decre	easeu								
Medicine				2000					
ZOLOFT (Su			400 0 M:III	Reas	on: Daily		Oral		
Tablet 3atch:		24.0	100.0 Milligram Started:			Stopped:	Orai		
Jalu)(d	irteu.			Morpheu.			
aborato	ry Investigatio	ons:							
Date	Туре	Range	Date Tested	Result			Details	3	
Additiona	I Information	•							
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Re	no	rt	D	eta	i
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Case Number: 150629 Seq: 1 Gender: F
Reported: 21/03/2000 Weight:
Hospitalisation: Age: 16Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Therapeutic response decreased			

Medicine Details:

GINSENG (Interaction)		Reason:	
Oral application	0.0		Oral
3atch:	Started:	Stopped:	
VITAMIN B COMPLEX (Interaction)		Reason:	
Oral application	0.0		Oral
Batch:	Started:	Stopped:	
ZOLOFT (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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.



q: 1 everity Repo	Weig A Do Causal rt Description	ge: 70Y DB: lity: Causality possible Treatment
	Weig A Do Causal rt Description	ght: ge: 70Y OB: lity: Causality possible Treatment
everity Repo	A D(Causal rt Description	ge: 70Y DB: lity: Causality possible Treatment
everity Repo	Causal rt Description	OB: lity: Causality possible Treatment
everity Repo	Causal rt Description	lity: Causality possible Treatment
everity Repo	rt Description	Treatment
everity Repo		
everity Repo		
		Isordil ceased.
202	- Con-	
	•	CONTIN
Date Tested Result	T	Details
	0.0 Started: 100.0 Milligram Started:	Reason: Depression 100.0 Milligram Daily Oral Started: Stopped:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

FEFOL (Suspected)							
Capsule	1.0	Dose Unspecified	Daily	Oral			
3atch:	Started:		3t	opped:			
BLACKMORES PREGNANCY AND BRE	BLACKMORES PREGNANCY AND BREAST-FEEDING FORMULA (Sus Reason:						
Capsule	2.0	Dose Unspecified	Daily	Oral			
3atch:	Started:		3t	opped:			
L.							
ZOLOFT (Suspected)		Reas	on:				
ZOLOFT (Suspected)	25.0		on: Daily				
ZOLOFT (Suspected) 3atch:	25.0 Started:		Daily	opped:			
			Daily St	opped:			
Batch:		Milligram	Daily St	opped: Oral			

Laboratory Investigations:

	<u> ,</u>				
Date	Туре	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.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Case Number:	150687	Seq: 1			Gender:	F	
Reported:	21/03/2000				Weight:		
Hospitalisation:					Age:	31Y	
Onset Date:					DOB:		
	Not yet recovered	d			Causality:	Causality possible	
Reaction Detai							
Medicine Deta	ails:						
CARDIPRIN 100 (S				Reason:			
Tablet		100.0	Milligram	Daily	Oral		
3atch:		Started:		3	topped:		
Laboratory In	voetigatione						
Laboratory III	vestigations.						
A .1.1141 1.1.6							
Additional Info		orn to a differen	at father has	tuborous soloro	cic		
o other sibilitys iff is	anniy. One brother t	Join to a uniterer	it iaulti lid	aberous sciero	JIJ.		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

		<u>-</u>	<u> </u>
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
 Daily
 Oral

 3atch:
 3tarted:
 08/02/2000
 3topped:
 09/02/2000

Laboratory Investigations:

Date	Туре	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.

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

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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Symptoms resolved after zoloft is reintroduced.



Report De	etail						
Repor Hospitalisat Onset D					DC	ht: ge: A5 DB:	0
Outco Reaction D					Causan	ity: Causality possibl	е
	eferred Term	Severity	Repo	ort Description		Treatment	
Anxiety Tremor			Patient felt anxio	ous.		Zoloft was ceased.	
	Deteiler						
Medicine ZOLOFT (Su			Rea	ison: Depres	sion		
Table		50	Reason: Depression 50.0 Milligram Daily Oral				
		50	.0 Milligram	Daily	Oral		
3atch		Started:	.0 Milligram		Oral ped:		
Laborator	ry Investigat	Started:			ped:	Potoilo.	
	h:	Started:			ped:	Details	



		,,						
Report De	etail							
Repor Iospitalisat Onset D			1			Weiç A De	ige: OB:	ality possible
eaction D		0		D	. D			
Rash erythe	eferred Term	Sev	erity	Repor ent developed	Descriptio		I	reatment
Medicine ZOLOFT (Su				Reas	on: Depre	ession		
Table			100.0 Milli		Daily	Oral		
3atcl	1:	3ta	ırted:		3to	pped:	CC	NTIN
Laborato i Date	r y Investigat	i ions: Range	Date Tested	Result			Details	
Date	туре	Range	Date Testeu	Result			Details	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

odotion Botal						
Preferred Term	Severity	Report Description	Treatment			
Nausea		Pt experienced naused whil on 25mg, 50mg & 75mg.				
Hepatic function abnormal						

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

75.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

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

Additional Information:

Nausea subsided after each dosage increase.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

 3atch:
 3tarted:
 08/03/2000
 3topped:
 22/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient did not previously have acne.



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

Rep	ort	Detail
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Case Number:150826Seq:1Gender:FReported:27/03/2000Weight:Hospitalisation:Admitted to hospitalAge:21Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

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

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Detail							
Case Number:	150835	Seq:	1			Gender:	
Reported: 2	27/03/2000					Weight:	0.00
Hospitalisation:						Age:	15Y
Onset Date:						DOB:	
Outcome: \	Jnknown					Causality:	Causality possible
Reaction Detai	_	1 _	1			<u> </u>	
Preferred		Sev			Description		Treatment
Tourette's disorde	r		Tic	s due to Touret	te's syndrome w	rere	
Tic							
Medicine Deta				Reas	on:		1
,	G,		2.0 M	illigram	Daily		
3atch:		3ta	rted:		Stoppe	d:	
ZOLOFT (Suspected	d)			Reas	on: Depression	n	
			25.0 M	illigram	Daily	Oral	
3atch:		3ta	irted:		Stoppe	d:	
Laboratory Inv	vestigation	s:					
		Range	Date Tested	l Result		Deta	ils



	er: 15083	•	1						ler: F		
-	ed: 27/03/	2000						Weig	•		
ospitalisati Opeot Da	on: ate: 24/02/:	2000							ge: 84Y)B :		
	ne: Recov						C			sality possible	_
action De		cica						ausai	ity. Oau	isality possible	C
	erred Term	Sev	erity		Report I	Desc	ription			Treatment	
rythema mu			,		- 1					oloft and risper	ridor
edicine [Reasor	1:	Depression				
Tablet	t		50.0	Milligram	Г	Daily		Oral			
3atch:	:	3ta	arted:				Stopped:				
RISPERIDONI	E (Suspected)			Reasor	1:	Unspecified p	sychosi	S		
Tablet				Milligram	[Daily		Oral			
3atch:		St:	arted:				Stopped:				
aborator	y Investig Type	gations:	Date Tes	sted F	Result				Details		
Date											



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

TAZAC (Other drug)	Reason:				
	600.0 Milligram	Daily			
Зatch:	Started:	Stopped:			
ZOLOFT (Suspected)		Reason: Depression			
T	25.0 Milliarom	Deily	ral		
Tablet	25.0 Milligram	Daily O	ral		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No prior use of antidepressants.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Gender: F Seq: 1 Reported: 28/03/2000 Weight: 84.00

Hospitalisation: Age: 56 **DOB:** 31/10/1943

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date:

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	
3atch:	Started:	L TERM	Stopped:	
SERTRALINE HYDROCHLORIDE (Suspec	ted)	₹eason:		
Tablet	200.0 Milligram	Daily	Oral	
3atch:	3tarted: 01/01/1997		Stopped:	
FOSINOPRIL (Suspected)		Reason:		
Tablet	10.0 Milligram	Daily	Oral	
3atch:	3tarted: 01/01/1997		Stopped:	
ALLOPURINOL (Suspected)		₹eason:		
Tablet	150.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	

Laboratory Investigations:

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

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

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 Detai

Medicine Details:

PRAVASTATIN SODIUM (Suspected)		Reason:		
Tablet	40.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1996	Stopped	l : 04/02/2000	
100000000000000000000000000000000000000				
ISOSORBIDE MONONITRATE (Suspected)		Reason:		
Tablet Tablet	60.0 Milligram	Reason: Daily	Oral	

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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase in		i isperi – seeripiiei	
Convulsion			Dilartin tds ivi, acylovir ivi (hsv possible) 500mg tds x 4 doses. zoloft (sertraline ceased).
Hyperpyrexia Hyperreflexia Hypertonia			

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression	
	100.0 Milligram	Daily		
3atch:	Started: 26/11/1999		Stopped:	29/11/1999
LITHIUM CARBONATE (Suspected)		Reason:		
Tablet	1.5 Gram	Daily		Oral
3atch:	Started:		Stopped:	02/12/1999
THIORIDAZINE HYDROCHLORIDE (Sus	spected)	Reason:	Otr spec symp	psychopathol nec
	100.0 Milligram	Daily		
3atch:	Started: 27/11/1999		3topped:	29/11/1999

Laboratory Investigations:

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

Additional Information:

Serotonin syndrone most probable neuroleptic malignant syndrome.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 24/02/2000 3topped: 09/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Repo	rt D	etail
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

3atch: Started: STERM Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Medicine Details: ZOLOFT (Suspected) Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped:	Preferred Term Severity Report Description Treatment	ospitalisatio Onset Dat Outcom	te: ne: Recovered	Seq: 1				Weig A D	der: F ght: Age: OB: lity: Causality possible
leadache fluscle twitching lausea Indicine Details: Indicine	Redicine Details: ZOLOFT (Suspected) Tablet 100.0 Milligram Daily Oral Satch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral Satch: Started: Stopped: Aboratory Investigations: Date Type Range Date Tested Result Details			Severi	ty	Report Des	cription		Treatment
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Reason: Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped:	Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: Date Type Range Date Tested Result Details	leadache				·	·		
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped:	Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped:								
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped:	Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped:								
ZOLOFT (Suspected) Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped:	Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: Started: Daily Oral According to the started of the s								
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: TRYPTOPHAN (Suspected) Ceason: Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped:	Tablet 100.0 Milligram Daily Oral 3atch: 3tarted: 3topped: TRYPTOPHAN (Suspected) Reason: Oral application 1.0 Gram Daily Oral 3atch: 3tarted: 3topped: Aboratory Investigations: Date Type Range Date Tested Result Details								
3atch: Started: Stopped: TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: Aboratory Investigations:	Started: Stopped: TRYPTOPHAN (Suspected) Reason: Oral application 1.0 Gram Daily Oral Started: Stopped: Stopped: Stopped: Started: Stopped: Oral Started: Stopped: Oral Started: Stopped: Oral				400 0 Million			01	
TRYPTOPHAN (Suspected) Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: aboratory Investigations:	Application 1.0 Gram Daily Oral 3atch: Started: Stopped: Application 1.0 Gram Daily Oral			Starte		ram Daily		Orai	
Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: aboratory Investigations:	Oral application 1.0 Gram Daily Oral 3atch: Started: Stopped: aboratory Investigations: Date Type Range Date Tested Result Details		(Suspected)	Jiante	u.	Reason:	Moppeu.		
aboratory Investigations:	.aboratory Investigations: Date Type Range Date Tested Result Details				1.0 Gram			Oral	
aboratory Investigations:	aboratory Investigations: Date Type Range Date Tested Result Details Details			Starte		,			
Date Type Range Date Tested Result Details									
	Additional Information:				1	I			
	Additional Information:				Date Tested	Result			Details
					Pate Tested	Result			Details
Additional Information:		Date	Туре	Range D	Pate Tested	Result			Details
Additional Information:		Date	Туре	Range D	Pate Tested	Result			Details



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

$NM \sim M$	IAIRA	110+01	\sim
IVIECI	10:1110	Detai	•
		Dotai	

ZOLOFT (Suspected)		Reason:	
	50.0 Milligram	Daily	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



DOB: 15/08/1954

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

Outcome: Unknown Causality: Causality possible

Reaction Detai

Onset Date:

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

Medicine Details:

CLOZARIL (Suspected)		Reason:	Unspecified schizophrenia	
Tablet	700.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/1995		Stopped:	CONTIN
SERTRALINE HYDROCHLORIDE (Susp	ected)	Reason:		
	150.0 Milligram	Daily		
3atch:	Started:		Stopped:	
ATENOLOL (Suspected)		Reason:		
	50.0 Milligram	Daily		
3atch:	Started:		Stopped:	
ATORVASTATIN (Suspected)		Reason:		
	20.0 Milligram	Daily		
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Radiololgy				Mild dilated Iv and mild decrease in systolic function, apex hypokinesia. ie. Iv 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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal			_
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:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report D)etail
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 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hallucination			None.

Medicine Details:

ZOLOFT (Suspected) Reason: Anxiety neurosis

25.0 Milligram Daily

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred two weeks after starting zoloft.



		, .,,				
Report De	etail					
Repor Hospitalisat Onset D Outco	ome: Recovere		1		С	Gender: M Weight: Age: 68Y DOB: ausality: Causality possible
Reaction D	eferred Term	Seve	erity	Report	Description	Treatment
Palpitations						Zoloft was reduced from 50mg to 25mg daily.
Medicine ZOLOFT (Su				Reaso	on: Depression	
3atcl			50.0 Milli	gram	Daily Stopped:	
Laborato	ry Investigat	ions:				
Date	Type	Range	Date Tested	Result		Details
Additiona	ıl Informatio	n:				



Report Detail						
Case Number: 15	1461 Seq:	1		Ge	ender:	F
Reported: 10	-			W	eight:	
Hospitalisation:					Age:	A3
Onset Date: 21	/03/2000				DOB:	
Outcome: Re	covered			Cau	sality:	Causality possible
Reaction Detai		<u> </u>				
Preferred T	erm Sev	erity	Report	Description		Treatment
Rash		Rash	consisting of	pin point red spots.		
Medicine Details ZOLOFT (Suspected)	S :		Reaso	·		
Tablet		50.0 Milli	gram	Daily Or	al	
3atch:	Sta	arted:		Stopped:		
Laboratory Inve	stigations:					
Laboratory Inve		Date Tested	Result		Deta	ils
		Date Tested	Result		Deta	ils



Report Detail				
Case Number: 151462 Reported: 10/04/2000 ospitalisation: Onset Date:	Seq: 1			Gender: F Weight: Age: 10Y DOB:
Outcome: Not yet rec	covered		Ca	usality: Causality possible
action Detai				
Preferred Term	Severity	Report Des	scription	Treatment
icturition disorder				Reduced zoloft to 3/4 of a 50mg tablet.
ledicine Details: ZOLOFT (Suspected) Tablet	50.0 N	Reason:		pulsive neurosis Oral
Batch:	50.0 M Started:	filligram Daily	Stopped:	Orai
.aboratory Investigation	Ons: Range Date Tester	d Result		Details
Laboratory Investigation Date Type Additional Information	Range Date Tester	d Result		Details
Date Type	Range Date Tester	d Result		Details



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms 6 months after starting zoloft 50mg.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 151465 Reported: 10/04/2000 espitalisation: Onset Date: Outcome: Not yet recoraction Detai	Seq: 1	Gender: F Weight: Age: DOB: Causality: Causality possible		
Preferred Term	Severity	Report Do	escription	Treatment
pecia				
edicine Details: OLOFT (Suspected)	0.0	Reason:	Depression	
3atch:	0.0 Started:		Stopped:	CONTIN
aboratory Investigatio	ns:			
Date Type	Range Date Tested	Result	[Details
dditional Information:				
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

<u></u>		
ZOLOFT (Suspected)	Reaso	on:
	0.0	
Зatch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Case Number: 151555 Reported: 12/04/2000 Iospitalisation: Onset Date: Outcome: Unknown eaction Detai Preferred Term Mania Hypoaesthesia	Seq: 1	Report Increase in manic s	Weig A DO Causal Description	der: F ght: ge: 26Y DB: ity: Causality possible Treatment	
ospitalisation: Onset Date: Outcome: Unknown eaction Detai Preferred Term	Severity		A DO Causal Description	ge: 26Y OB: ity: Causality possible	
Onset Date: Outcome: Unknown eaction Detai Preferred Term Mania	Severity		Causal Description	OB: ity: Causality possible	
Outcome: Unknown eaction Detai Preferred Term Mania	Severity		Causal Description	ity: Causality possible	
Preferred Term Mania	Severity		Description		
Preferred Term Mania	Severity			Treatment	
Mania	Seventy			пеашеш	
		increase in manic s	umntomo		
туроасынсыа			ymptoms.		
Medicine Details: ZOLOFT (Suspected)		Reaso	n: Depression		
Tablet	50.0		Daily Oral		
3atch:	Started:	-	Stopped:		
_aboratory Investigations	s:				
	Range Date Te	ested Result		Details	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

Medicine Details.					
ZOLOFT (Suspected)		र	eason: De	epression	
Tablet	50.0	Milligram	Daily	Oral	
3atch:	Started:			Stopped:	
INDOCID (Suspected)		5	eason:		
Capsule	150.0	Milligram	Daily	Oral	
3atch:	Started:	L TE	DM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Causality: Causality possible

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

Report [Detail
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Case Number:151565Seq: 1Gender:FReported:11/04/2000Weight:Hospitalisation:Age: AD

Onset Date: DOB:

Reaction Detai

Outcome: Unknown

Caction Detai	-	_	
Preferred Term	Severity	Report Description	Treatment
Somnolence neonatal			

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



eport De								
	oer: 151575	Seq: 1	1			Gender:	M	
Report	ed: 12/04/2000					Weight:		
pitalisati	on:					Age:	50Y	
Onset Da	ate:					DOB:		
Outcor	ne: Not yet recov	/ered				Causality:	Causality poss	ible
ction D						•		
	erred Term	Sever	rity	Repo	rt Description		Treatment	
ido decrea	ased							
edicine I	pected)		50.0 Milli	Reas				
Table		.	50.0 Millio	gram	Daily	Oral		
3atch	•	3tart			Stopped	•		
borator	y Investigatio	ns:						
Date	Туре		Date Tested	Result		Details	3	
Iditional	Information:							
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Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 151576	Seq: 1		Gend	
Reported: 12/04/2000			Weig	
spitalisation:				ge: 32Y
Onset Date:			DC	
Outcome: Not yet recov	ered		Causali	ty: Causality possible
oction Detai	Carranita	Danas	4 December	Tuestuesest
Preferred Term	Severity		t Description	Treatment
ausea		Exacerabation of i pregnancy	nausea & vomitng due to	
omiting		, ,		
edicine Details: OLOFT (Suspected)		Reas	on: Depression	
Tablet	25.0	Milligram	Daily Oral	
3atch:	Started:	g	Stopped:	
aboratory Investigation Date Type	Range Date Te	sted Result	Г	Details
Date Type	Trange Date 16	sted Result		Jetalis .
dditional Information:				
ort Run 27/07/200 03:26PN [



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

ospitalisati Onset Da		Seq: 1				Gender: Weight: Age: DOB: ausality:	60Y
action D						aasanty.	Caddanty possible
	ferred Term	Severity	1	Report De	scription		Treatment
lyponatraen	nia			·	·		
ledicine l				₹eason:			
LOOLO (Othe	, arug)		0.0	(cason.			
3atch	:	Started:			Stopped:		
ASPIRIN (Oth				Reason:			
			0.0				
3atch	:	Started:			}topped:		
ZOLOFT (Sus	spected)			Reason:	Depression		
Table	et	5	50.0 Millig	gram Dai	-	Oral	
Table		\$4 d d -					
3atch	:	Started:			Stopped:		
3atch	y Investigatio	ns:	e Tested	Result	Stopped:	Deta	ils



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

Report D)etail
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Case Number: 151578 Seq: 1 Gender: U
Reported: 12/04/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

toaction Botal		<u> - </u>	
Preferred Term	Severity	Report Description	Treatment
Purpura		Bleeding into skin-red blotches.	
Nausea		Severe nausea	
Dizziness			

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

3atch:

\$topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report Detail	Re	ро	rt C	Deta	il
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Case Number: 151580 Seq: 1 Gender: M
Reported: 12/04/2000 Weight:

Hospitalisation: Age: 30Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

todotion botal			
Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			
Nightmare			

Medicine Details:

ZOLOFT (Suspected)

Tablet

100.0 Milligram

Daily

Oral

Started:

Stopped:

Laboratory Investigations:

Date	Туре	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.



	51581	Seq: 1	1				Gend	der: M		
Reported: 12		•					Weig			
spitalisation:								.ge:		
Onset Date:								OB:		
Outcome: Re	ecovered					C	ausal	l ity: Cau	sality pos	sible
action Detai	_		_				_	_		
Preferred T	erm	Sever	rity	Repoi	t Descrip	tion			Treatme	nt
somnia							1	Zoloft was from 100r	s reduced ng daily.	to 50mg
edicine Detail OLOFT (Suspected)										
-OLOI I (Suspecteu)				teas	on: De	pression				
Tablet			100.0 Mill			pression	Oral			
		3tart	100.0 Mill ed:		Daily	Stopped:	Oral			
Tablet		Start			Daily		Oral			
Tablet	estigations				Daily			Details		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:

Reported: 12/04/2000 Weight:
Hospitalisation: Age: A4

Onset Date: 28/03/2000 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Fatigue		Severe lethargy	
Asthenia			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

 Tablet
 50.0 Milligram
 1 time
 Oral

 3atch:
 3tarted:
 28/03/2000
 3topped:
 28/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after taking one 50mg zoloft tablet.



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

Report I	Detail
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Rash			Prednisone.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

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 Detai

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

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



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

Report [Detail
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Case Number: 152054 Seq: 1 Gender: F
Reported: 26/04/2000 Weight:
Hospitalisation: Age: 42Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

			=
Preferred Term	Severity	Report Description	Treatment
Leukocytosis			Zoloft ceased
Leukocytosis			

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 300.0 Milligram
 Daily
 Oral

 3atch:
 Started:
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced similar reaction while on paroxetine.



Domant Datail						
Case Number: 152055	Seq: 1			nder: F		
Reported: 26/04/2000 ospitalisation:				ight:		
Onset Date: 10/04/2000				Age: A6 DOB:		
Outcome: Recovered		Causality: Causality possibl				
eaction Detai				unity: Gaddanity possible		
Preferred Term	Severity	Repor	Description	Treatment		
Somnolence			days after taking one	Zoloft ceased		
/ledicine Details:						
ZOLOFT (Suspected)		Reas	on: Depression			
Tablet	50.0) Milligram	Daily Ora	I		
3atch:	Started:		Stopped:	1W		
_aboratory Investigatio	ns: Range Date Te	ested Result		Details		



Report Det	ail						
Case Numb		Seq:	1			Gender:	F
	ed: 26/04/200	0				Weight:	
ospitalisatio						Age:	
Onset Da						DOB:	
	ne: Not yet re	covered			C	ausality:	Causality possible
action De		<u> </u>	-				
	erred Term	Sev	erity	Report	Description		Treatment
ash maculo-	-papular					Zolo	ft ceased
f odicino P	2444						
ledicine D				Reaso	n: Depression		
Tablet			50.0 Mill		Daily	Oral	
3atch:		Sta	irted:	ngram	Stopped:	Olui	1W
	∕ Investigat						
_aboratory Date	/ Investigat Type	ions: Range	Date Tested	Result		Deta	ils



Report Deta	ail							
Case Numbe Reporte Iospitalisatio Onset Dat	d: 26/04/200 n:	Seq: 1				Gender: F Weight: Age: 3 DOB:		
	e: Not yet re	covered			С	ausality: (Causality possil	ble
eaction Det		<u> </u>	Ī					
Prefe Galactorrhoea	rred Term	Severity		Report Desc	cription		Treatment	
Medicine D ZOLOFT (Susp Tablet 3atch:		100 Started:	0.0 Milligram	₹eason: Daily	Depression Stopped:	Oral	CONTIN	
Laboratory Date	Investigat Type		Tested F	Result		Details		
Additional l	Informatio	n:						



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

Report Detail	Re	po	rt	D	eta	i
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Case Number: 152061 Seq: 1 Gender: F
Reported: 26/04/2000 Weight:

Hospitalisation: Age: 16Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOLOFT (Suspected)

Tablet

10.0 Milligram

Daily

Oral

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred four years after starting zoloft therapy.



		, .,, ,						
Report Det	ail							
_	d : 26/04/200	Seq:	1			We	ider: M ight:	
Hospitalisatio							Age : 25	Y
Onset Dat	te: ie: Recovere	d					OB:	vuodity poosiblo
Reaction De		u				Causa	anty. Ca	usality possible
	erred Term	Sev	erity	Repor	t Description	<u> </u>		Treatment
Nausea		Severe						
Medicine D				Reas	on: Depres	sion		
Tablet	,		50.0 Milli		Daily	Oral		
3atch:		3ta	arted:		}top	ped:		CONTIN
Laboratory Date	· Investigat	ions:	Date Tested	Result			Details	
Date	туре	Range	Date Tested	Result			Details	



eport Detail									
ase Number:	152063	Seq: 1				Gender:	F		
Reported: 26/04/2000			Weight:						
spitalisation:						Age:	30Y		
Onset Date:						DOB:			
Outcome:	Recovered				Causality: Causality possible				
ction Deta		1	<u> </u>			-			
Preferre	ed Term	Severi	ty	Repo	rt Description		Treatment		
trorrhagia						I			
aliaina Da4									
edicine Det				Rea	son: Depression	n			
Tablet			50.0 Millio		Daily	Oral			
3atch:		Starte		g. w	Stoppe				
	vestigatio		ate Tested	Danult	<u> </u>	Data	:1-		
Date	Туре	Range D	ale resieu	Result	+	Deta	IIS		
lditional In	formation:	·							
t Run 27/07/20	0 03:27PN	Database: pusin	ne		ADRS004		Page 157 of 59		



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

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8		 .,	-14	
Re	\sim	 _	U LU	

Case Number: 152064 Seq: 1 Gender: F
Reported: 26/04/2000 Weight:
Hospitalisation: Age: 35Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Breathlesness	
Dizziness			
Headache			
Myalgia			

Medicine Details:

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

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced the following symptoms while scuba diving.



Report Detai							
Case Number:	152065	Seq:	1			Gend	ler: M
Reported:	26/04/200	0				Weig	jht:
Hospitalisation:						Α	ge: 50Y
Onset Date:							OB:
Outcome:	Unknown					Causal	ity: Causality possible
Reaction Deta						1	
	ed Term	Seve	rity	Repor	Description		Treatment
Ejaculation failu	re						
Medicine Det				Reas	on: Depression		
Tablet	iou,		50.0 Milli		Daily	Oral	
3atch:		Star		9	Stopped:		
Laboratory I	าvestigati	ions:					
Date	Туре		Date Tested	Result			Details
Additional In	formation	1:					



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Reported: 26/04/2000 lospitalisation: Onset Date: Outcome: Unknown eaction Detai Preferred Term Anorgasmia Breast pain					Wei	ght:
Onset Date: Outcome: Unknown action Detai Preferred Term norgasmia						-
Outcome: Unknown action Detai Preferred Term norgasmia						\ge : 35Y
Preferred Term norgasmia						OB:
Preferred Term norgasmia					Causa	lity: Causality possible
norgasmia	1 0 11					- , ,
	Severit	У	Repo	rt Description	<u>n</u>	Treatment
raaet nain						Zoloft ceased
Medicine Details:						
ZOLOFT (Suspected)		50.0 M:U	Reas		0.1	
Tablet 3atch:	50.0 Milligram			Daily	Oral	2M
Satcii.	Started	1.		310	pped:	ZIVI
_aboratory Investigations		ate Tested	Result			Details



Report Detail Case Number: 152118 Reported: 28/04/2000 Iospitalisation: Onset Date: Outcome: Recovered eaction Detai Preferred Term	Seq: 1		Gender: Weight: Age: DOB: Causality:	50Y
Preferred Term			- augunty.	Causality Dossible
Preferred Term				edudanty possible
	Severity	Report De	scription	Treatment
Diarrhoea	P€	ersistant diarrhoea	Cea com	sed aoloft and menced cipramil.
Medicine Details: ZOLOFT (Suspected) Tablet	100.0 N	Reason: ∕Iilligram Dail	Depression y Oral	
aboratory Investigations:				
Date Type Ran	ge Date Teste	d Result	Deta	ils



Additional Information:

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

eport Detail ease Number: 152119	Seq: 1		Gend	ler: M
Reported: 28/04/20	-		Weig	
spitalisation:			_	ge: 40Y
Onset Date: 11/04/20	00		DC	OB:
Outcome: Not yet re	ecovered		Causal	ity: Causality possible
action Detai			1	
Preferred Term	Severity	Report D	escription	Treatment
ausea			<u> </u>	Reduced zoloft from 50mg to
adiaina Dataila				
		Reason :	: Depression	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected)	50.0 Started:			
			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet			aily Oral	
OLOFT (Suspected) Tablet 3atch:	Started:		aily Oral	
Tablet 3atch: aboratory Investiga	Started:	Milligram D	aily Oral	
OLOFT (Suspected) Tablet 3atch:	Started:	Milligram D	aily Oral	Details
Tablet 3atch: aboratory Investiga	Started:	Milligram D	aily Oral	Details
Tablet Batch: aboratory Investiga	Started:	Milligram D	aily Oral	Details
Tablet Batch: aboratory Investiga	Started:	Milligram D	aily Oral	Details
Tablet Batch: aboratory Investiga	Started:	Milligram D	aily Oral	Details
Tablet Batch: aboratory Investiga	Started:	Milligram D	aily Oral	Details



Report Detail						
Case Number: 152120 Reported: 28/04/2000 ospitalisation:	Seq: 1				Gender: Weight: Age:	
Onset Date:					DOB:	
Outcome: Recovered				С	ausality:	Causality possible
action Detai						
Preferred Term	Severity	,	Repo	rt Description		Treatment
remor					Zolo 50m	ft reduced from 100mg to g daily.
edicine Details: ZOLOFT (Suspected)			₹ea	son: Depression		
Tablet	1	00.0 Millig	gram	Daily	Oral	
3atch:	Started:	:		Stopped:		
_aboratory Investigation		te Tested ┃	Result		Deta	ils
- Type	range Dat	ic resieu	result		Deta	110
Additional Information:						
Additional Information:						



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Reported: 28/04/2000 ospitalisation: Onset Date: Outcome: Recovered	Seq: 1	Weight: Age: DOB: Causality: Causality possible				
Preferred Term	Severity	Report De	scription	Treatment		
ash		·	-			
edicine Details:	0.0	Reason:	Depression			
3atch:	0.0 Started:		Stopped:			
aboratory Investigatio						
Date Type	Range Date Tested	Result		Details		
dditional Information:	,	•				
ort Run 27/07/200 03:27PN	Database: pusime	ADRS	004	Page 164 of 591		



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number	: 152123	Seq:	1		Ger	nder: U
	: 28/04/200	_				ight:
Hospitalisation						Age:
Onset Date	:					OOB:
Outcome	: Recovere	d			Causa	ality: Causality possible
Reaction Deta	ai					
Preferr	ed Term	Seve	erity	Report	Description	Treatment
Rash						
Medicine De						
ZOLOFT (Suspec	cted)			Reaso	on: Depression	
			0.0			
3atch:		3ta	rted:		Stopped:	
Laboratory I						
Date	Туре	Range	Date Tested	Result		Details
Additional Ir	nformatio	n:				
eport Run 27/07/2	00 03:27PN	Database: pu	sime	Α	DRS004	Page 165 of 591



Report Det	tail						
		Seq: 1				Gender: F Weight: Age: 3 DOB:	00Y
	ne: Not yet red	covered			C	ausality: (Causality possible
eaction De		0		Dt D	and the Control	-	Totalogical
Prete Weight increa	erred Term	Severity		Report D	escription		Treatment
Medicine [ZOLOFT (Sus Tablet 3atch:	pected) t	1 Started:	00.0 Milligra	Reason: am Da	Depression aily Stopped:	Oral	CONTIN
Laboratory Date	y Investigati Type		e Tested	Result		Details	
Additional	Information	ղ:					



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

lospitalisatio Onset Da Outcor	ed: 28/04/200 on: ite: ne: Recovere		1	Gender: U Weight: Age: DOB: Causality: Causality possible			ible	
eaction De	etai erred Term	Seve	erity	Report	Description		Treatment	
Rash					555p.11011			
Medicine [ZOLOFT (Sus	Details: pected)			Reaso	on: Depression			
3atch:		240	0.0 rted:		Stopped:			
Laboratory	y Investigat	ions:						
Date	Туре	Range	Date Tested	Result		Details		
Additional	Informatio	n:						
eport Run 27/0	7/200 03:27PN	Database: pu	sime	Al	DRS004		Page 167	of 591



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Sudden death			

Medicine Details:

TEGRETOL (Suspected)		Reason:	Depression	
Tablet	400.0 Milligram	Daily		Oral
3atch:	Started: 29/12/1998		Stopped:	13/01/1999
SERTRALINE HYDROCHLORIDE	(Suspected)	Reason:	Depression	
Tablet	100.0 Milligram	Daily		Oral
3atch:	Started: 29/12/1998		Stopped:	13/01/1999
DIAZEPAM (Suspected)		Reason:		
Oral application	5.0 Milligram	Daily		Oral
3atch:	Started: 29/12/1998		Stopped:	13/01/1999

Laboratory Investigations:

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

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.

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

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Case Number: 152363 Seq: 1 Gender: F
Reported: 04/05/2000 Weight:
Hospitalisation: Age: A3

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Deafness		Hearing impairment.	

Medicine Details:

wedicine Details:				
AVAPRO (Suspected)	Reason:			
	0.0			
3atch:	3tarted: 01/01/1999		Stopped:	
CHLORPROMAZINE HYDROCHL	ORIDE (Suspected)	Reason:		
	0.0			
3atch:	Started:		Stopped:	
SERTRALINE HYDROCHLORIDE	(Suspected)	Reason:		
	0.0			
Зatch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

		eta	

 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 Detai

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 01/09/1999 3topped: 01/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Caction Detai			
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		
3atch:	Started:		Stopped:		4W	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms while taking zoloft for 4 weeks.



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

Report D)etail
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Case Number:152495Seq: 1Gender: FReported:10/05/2000Weight:Hospitalisation:Admitted to hospitalAge: A8

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			
Orthostatic hypotension			

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

Modifile Botalies				
ZOLOFT (Suspected)		Reason:	Depression	
Tablet	150.0 Milligram	Daily	Oral	
Зatch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	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.



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

Report Detail	Re	ро	rt C	Deta	il
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 Case Number:
 152510
 Seq: 1
 Gender: M

 Reported:
 10/05/2000
 Weight:

Hospitalisation: Age: 40Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

3atch:

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after 1 week of zoloft therapy.



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

Report [Detail
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 Case Number:
 152511
 Seq: 1
 Gender:
 F

 Reported:
 10/05/2000
 Weight:

 Hospitalisation:
 Age: A5

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason:

100.0 Milligram Daily

3atch: 3tarted: 01/01/1998 **3topped:**

Laboratory Investigations:

Date	Туре	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.



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

Report [Detail
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 Case Number:
 152622
 Seq: 1
 Gender:
 F

 Reported:
 15/05/2000
 Weight:

Hospitalisation: Age: 72Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: Started: Stopped: 6W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: 3tarted: 15/04/2000 **3topped:** 01/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report D)etail
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 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 Detai

• '	touction botal			
	Preferred Term	Severity	Report Description	Treatment
	Somnolence			

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 25.0 Milligram 1 time Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after one dose of 25mg zoloft.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: 3tarted: 04/04/2000 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Laboratory Investigation Date Type				<u> </u>			
	Range	Date Tested	Result		Deta	ails	
	ns:						
3atch:	3tart	eu.		3101	oped:		
Tablet	.	25.0 Millig	gram	Daily	Oral •		
Medicine Details: ZOLOFT (Suspected)			Reas	on:			
AllAlety							
Aggression Anxiety		Outb	ursts of temp	er.			
eaction Detai Preferred Term	Sever	rity	Repor	t Descriptior	า	Treatment	
Outcome: Recovered						: Causality possible	:
					Age: DOB:	: 6Y :	
lospitalisation: Onset Date:							



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected)

Tablet
25.0 Milligram
Daily
Oral

Started:
Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Case Number: 152825 Seq: 1 Gender: F Reported: 22/05/2000 Weight: ospitalisation:	Report D	Detai l					
Onset Date: Outcome: Not yet recovered Search Severity Report Description Treatment Preferred Term Severity Report Description Treatment Normochromic normocytic anaen Medicine Details: UREX (Other drug) Reason: 0.0 3atch: Started: Storped: TEMAZE (Other drug) Reason: 0.0 3atch: Started: Storped: ATIVAN (Suspected) Reason: 0.0 3atch: Started: Storped: COVERSYL (Suspected) Reason: 0.0 3atch: Storped: COVERSYL (Suspected) Reason: 0.0 3atch: Storped: COVERSYL (Suspected) Reason: 0.0 3atch: Storped: COVERSYL (Suspected) Reason: 0.0 0.0 3atch: Storped: 0.0 3atch: Storp	Repo	orted: 22/05/200	-	1		We	eight:
Outcome: Not yet recovered section Detail Preferred Term Severity Report Description Treatment Ormochromic normocytic anaen Details: Details: Details: Details: Details Det	-						~
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Preferred Term Severity Report Description Treatment Ormochromic normocytic anaen Iedicine Details: UREX (Other drug) Reason:		=	,0000100			Jaus	unty. Gausanty possible
Idedicine Details: UREX (Other drug)			Sev	erity	Repo	rt Description	Treatment
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Started: Started: Stopped:				0.0			
TEMAZE (Other drug) Reason: 0.0 3atch: Started: Stopped: ATIVAN (Suspected) 0.0 3atch: Started: Stopped: COVERSYL (Suspected) 3atch: Started: Stopped: 0.0 3atch: Started: Stopped: 0.0 3atch: Started: Stopped: Aboratory Investigations: Date Type Range Date Tested Result Details Histology The marrow shows erythroid hyperplasia and in the presence 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	2 at	ch:	240			Stannad:	
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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	Date	Type	Range	Date Tested	Result		Details
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		1	<u> </u>			imanow apiasia_iniiitration	or underwind invelogyspiasia

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.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	152825	Seq: 1			Gender:	F
Reported:	22/05/2000				Weight:	
Hospitalisation:					Age:	61
Onset Date:					DOB:	09/09/1938
Outcome:	Not yet recovere	d			Causality:	Causality possible
Reaction Detail	İ					
Medicine Det	ails:					
PANADEINE FOR				Reason:		
		C	0.0			
3atch:		Started:			Stopped:	
FENTANYL CITRA	TE (Suspected)			Reason:		
		C	0.0			
3atch:		Started:			Stopped:	
ZOLOFT (Suspect	ed)			Reason:		
		C	0.0			
3atch:		Started:			Stopped:	
ZOTON (Suspecte	d)			Reason:		
		C	0.0			
3atch:		Started:			Stopped:	
Laboratory In	vestigations:					

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.



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

Report Detai	Re	po	rt	De	etai
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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 Detai

Medicine Details:

weatcine Details:				
LIPITOR (Suspected)		Reason:		
	0.0			
Зatch:	Started:		Stopped:	
AREDIA (Suspected)		Reason:	Malignant neoplasm of breast	
Injection, intravenous infusion	90.0 Milligram	Daily	Intravenous	
3atch:	3tarted: 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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis		Nightsweats.	
Headache		Retroorbital headache.	
Nausea			

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression		
Tablet	50.0 Milligram	Daily		Oral	
3atch:	Started: 15/05/2000		Stopped:	15/05/2000	
LIPITOR (Suspected)		Reason:	Othr&unspec	metabolic diseases	
	10.0 Milligram	Daily			
3atch:	Started: 13/04/2000		Stopped:	15/05/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression	
Tablet	25.0 Milligram	Daily		Oral
3atch:	Started:		Stopped:	10/05/2000

Laboratory Investigations:

Date	Туре	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.



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

Report D)etail
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 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 Detai

		1	·
Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Lip smacking, extensor posturing, jerky	
Rhinitis		Sneezy from 28/2/00-01/3/00.	
Drug withdrawal syndrome neons			
Nervousness			Baby was given iv antibiotics, gentamicin, penicillin, 24 hours post delivery then stop.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)

200.0 Milligram Daily

3atch: Started: L TERM Stopped: CONTIN

Laboratory Investigations:

Date	Туре	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.

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

Report	Detai∣
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Case Number: 153044 Seq: 1 Gender: F
Reported: 25/05/2000 Weight:
Hospitalisation: Age: 48Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

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

 3atch:
 3tarted:
 19/02/1999
 \$topped:
 21/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



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

Report D)etail
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 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 Detai

<u>touction betai</u>			
Preferred Term	Severity	Report Description	Treatment
Agitation			Required visit to a doctor
Hyperkinesia			
Insomnia			
Tremor			

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



eport Det	ail						
ase Numb	er: 153101	Seq:	1		Gende	er: M	
Reporte	ed: 25/05/2000	•			Weigh	nt:	
spitalisatio	n:				Ag	e:	
Onset Da	te:				DO	В:	
Outcom	ne: Unknown				Causality: Causality possible		
action De			•				
Prefe	erred Term	Seve	erity	Repor	t Description	Treatment	
sual disturb	ance		Seein	ig flashing lig	ht,while decreasing		
edicine D							
OLOFT (Susp			0.0	Reas			
Tablet		N	0.0		Oral		
3atch:		star	rted:		Stopped:		
aboratory	Investigation	ıs:					
Date	Туре	Range	Date Tested	Result	D	etails	
dd:4: a a a l	Information.						
aditional	Information:						
rt Run 27/07	7/200 03:27PN E	Database: pus	sime	Α	DRS004	Page 191	of 591



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (S	uspected)		30	eason:		
Tab	let	25.0	Milligram	Alternate	e days	Oral
3ate	eh:	Started:	L TEF	RM	Stopped:	28/02/2000

Laboratory Investigations:

Date	Туре	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.



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

Rep	ort	Detail
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Case Number: 153116 Seq: 1 Gender: U
Reported: 26/05/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

104011011 20141		-	
Preferred Term	Severity	Report Description	Treatment
Convulsion		Myoclonic jerks	
Hyperkinesia			

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression
Tablet	0.0	Daily	Oral
3atch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient is taking zoloft 100mg or 200mg.



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

Report D)etail
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Tachycardia			
Urinary retention			

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 25.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



eport Detail							
ase Number: 1		Seq: 1				Gende	
Reported: 2	26/05/2000					Weigh	
spitalisation:						Ag	
Onset Date: 2					_	DO	
Outcome: U	Jnknown				C	ausalit	y: Causality possible
action Detai Preferred	Term	Sever	ity	Penor	Description		Treatment
izziness	Tellii	Jever			ay of treatment.		rreatment
edicine Deta				Reas	on:		
Tablet			50.0 Mil	lligram	Daily	Oral	
					•		
3atch:		Starte	ed: 18/05/2	2000	Stopped:	22/05/2	000
.aboratory Inv	/estigatior	าร:	ed: 18/05/2	Result			etails
	v estination		ed: 18/05/2	2000		22/05/2	000



eport Detai∣							
ase Number: 153179	Seq: 1				Gender: F	=	
Reported: 19/05/2000					Weight:		
spitalisation:					Age: 2	22Y	
Onset Date:					DOB:		
Outcome: Not yet recov	ered				Causality: (Causality poss	ible
ection Detai					•	, ,	
Preferred Term	Severity		Repor	t Description		Treatment	
ills							
edicine Details:							
OLOFT (Suspected)			Reas	on: Depression			
Tablet	50	0.0 Milligr	ram	Daily	Oral		
3atch:	3tarted:			}topped	:		
aboratory Investigation							
Date Type		Tested	Result		Details	<u> </u>	
7.	9						
dditional Information:							



D (D ()			
Report Detail Case Number: 153183	Seq: 1	Gender	: M
Reported: 26/05/2000		Weight	
lospitalisation:			: 30Y
Onset Date: 09/05/2000		DOB	
Outcome: Recovered		Causality	: Causality possible
eaction Detai	Coverity	Depart Description	Tractment
Preferred Term Azoospermia	Severity	Report Description ow sperm count	Treatment
Medicine Details: ZOLOFT (Suspected) Tablet 3atch:	100.0 N Started:	Reason: Milligram Daily Oral L TERM Stopped :	
			oile.
Laboratory Investigation Date Type	S: Range Date Teste		ails



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Gender: F Seq: 1 Reported: 31/05/2000 Weight:

Hospitalisation: Treated in outpatient department only. Age: 25Y DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detail

Onset Date: 22/05/2000

		-	
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)	3	eason:	Other rheumatoid arthriti	S
Tablet	4.0 Dose Unspecif	ied Daily	Oral	
3atch:	Started: 01/04/2000		Stopped:	CONTIN
PREDNISOLONE (Suspected)	5	eason:		
Oral application	10.0 Milligram	Daily	Oral	
3atch:	Started: 01/01/2000		Stopped:	CONTIN
ZOLOFT (Suspected)	2	eason:		
Tablet	100.0 Milligram	Daily	Oral	
3atch:	Started: 01/06/1999		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

INTERFERON ALFA-2A (Suspected	i)	Reason:	Other diseases of liver	
Injection	0.0		Intravenous	
3atch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	Depression	
Tablet	100.0 Milligram	Daily	Oral	
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has been on zoloft for 10 weeks so far.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

Micalcinic Details.			
LOSEC (Suspected)	,	Reason:	
Oral application	0.0		Oral
Зatch:	Started: 01/04/2000	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started: 01/03/2000	Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion botal		_	<u> - </u>
Preferred Term	Severity	Report Description	Treatment
Abdominal pain		•	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

 3atch:
 Started:
 01/04/2000
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 153310 Reported: 31/05/2000 ospitalisation: Onset Date:	Seq: 1		Gender: F Weight: Age: 14Y DOB: Causality: Causality possible		
Outcome: Recovered					
Preferred Term	Severity	Repor	t Description	Treatment	
ausea					
ledicine Details:		No.	Devented		
ZOLOFT (Suspected) Tablet	25.0	Reas Milligram)ral	
Batch:	Started:	wiiiigram	Stopped:	nai	
aboratory Investigatio	ns:				
Date Type	Range Date Tes	ted Result		Details	
dditional Information:					
ort Run 27/07/200 03:27PN	Database: pusime	A	DRS004	Page 203 of 591	



Report De	etail						
	ber: 153375 ted: 01/06/200	Seq: 1				Gender: Weight:	
Hospitalisat							45Y
Onset D				DOB:			
	me: Recovere	d			C	ausality	Causality possible
eaction D	eferred Term	Severi	tv	Report	Description		Treatment
Palpitations		331311	•		egular heartbeat.	Cea	sed zoloft.
Medicine ZOLOFT (Su				Reaso	on: Depression		
Table	et		50.0 Milligram		Daily	Oral	
3atcl	ո։	Starte	ed:		Stopped:		
	ry Investigat		nata Tastad	Pacult		Det	sile.
Laborato Date	ry Investigat Type		Pate Tested	Result		Deta	ails



Severity	Report Descri	ption	
Severity	Report Descri	Age: DOB: Causality:	Causality possible Treatment
Severity	Report Descri	DOB: Causality:	Causality possible Treatment
Severity	Report Descri	Causality:	Treatment
Severity	Report Descri	ption	Treatment
Severity	Report Descri		
Seventy	Report Descri		
		Zolofi	ceased and auririx
	Reason:		
50.0 Milligra	am Daily	Oral	
Started:		Stopped:	
Date Tested	Result	Details	3
	Started:	50.0 Milligram Daily Started:	50.0 Milligram Daily Oral Started: Stopped:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected)			Reason:	
Tablet	50.0	Milligram	Daily	Oral
3atch:	Started:		3to	pped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

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 Detai

Report Detail

dotton botal						
Preferred Term	Severity	Report Description	Treatment			
Drug withdrawal syndrome						
Fatigue						
Myalgia						

Medicine Details:

IPRATROPIUM BROMIDE (Other drug)		Reason:
Inhalation	0.0	Inhalation
3atch:	Started:	Stopped:
ZOLOFT (Suspected)		Reason:
Tablet	0.0	Oral
3atch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason:

50.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:

Reported: 05/06/2000 Weight:
Hospitalisation: Age: 18Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOLOFT (Suspected)

Tablet

100.0 Milligram

Daily

Oral

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			
Renal impairment			

Medicine Details:

LOSEC (Suspected)		Reason:	Other diseases	of esophagus
	20.0 Milligram	Daily		
Зatch:	Started: 21/03/2000		Stopped: 1	6/05/2000
ZOLOFT (Suspected)		Reason:	Depression	
	50.0 Milligram	Daily		
3atch:	3tarted: 15/02/2000		Stopped: 1	6/05/2000

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
Onset Date: 11/05/2000
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

Medicine Details.				
LOSEC (Suspected)		Reason:	Other diseases of	esophagus
	20.0 Milligram	Daily		
Зatch:	3tarted: 21/03/2000		Stopped: 16/	05/2000
ZOLOFT (Suspected)		Reason:	Depression	
	50.0 Milligram	Daily		
3atch:	Started: 15/02/2000		Stopped: 16/	05/2000

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100000000000000000000000000000000000000		-	
Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities		Dandy walker syndrome.	Delivery at 5 months - still born
Intra-uterine death			

Medicine Details:

Medicine Details.			
DIAZEPAM (Suspected)		Reason:	
	20.0 Milligram	Weekly	
3atch:	Started:	Stopped:	
SERTRALINE HYDROCHLORIDE	(Suspected)	Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
3atch:	Started: 01/07/1999	Stopped:	28/11/1999

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Gender: F

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

Report Detail		

Seq: 1

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 Detai

Case Number: 153903

caction Detai							
Preferred Term	Severity	Report Description	Treatment				
Gingival hyperplasia	Required Specialist Consultation						

Medicine Details:

ZOLOFT (Suspected) Reason: Anxiety neurosis

100.0 Milligram Daily

3atch: 3tarted: 12/11/1999 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Report Detail

Case Number: 153992

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Reported: 21/06/2000 lospitalisation: Onset Date: Outcome: Unknown		Weight: Age: 28Y DOB: Causality: Causality possible				
Preferred Term	Severity	Reno	rt Description		Treatment	
Anxiety	Geventy	•	•	+	ricatinent	
Hyperkinesia		Extremely anxious and agitated. Legs were moving involuntarily.				
Serotonin syndrome		Serotonergic read				
Choreoathetosis	ļ	J				
ystonia	ļ					
lyperhidrosis						
lausea						
Palpitations						
Pruritus						
ALCOHOL (Suspected) Oral application 3atch:	20.0 Started:	Reas Gram	son: Total Stoppe	Oral		
SERTRALINE HYDROCHLORIDE (Suspected)	Reas	son:			
Tablet	50.0	Milligram	Daily	Oral		
3atch:	Started:		Stopped:			
_aboratory Investigatior Date Type	IS: Range Date Te	sted Result		Details		
Additional Information:						
oort Run 27/07/200 03:27PN [Database: pusime	,	ADRS004		Page 215 of 591	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Gender: F Seq: 1 Reported: 26/06/2000 Weight:

Hospitalisation: Age: 15Y **Onset Date:** DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

CLOZARIL (Suspected) Reason:

Tablet 400.0 Milligram Daily Oral

3tarted: 01/01/1999 3atch: Stopped: SERTRALINE HYDROCHLORIDE (Suspected)

50.0 Milligram Daily

Reason:

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:

Reported: 23/06/2000 Weight:
Hospitalisation: Age: 57

Onset Date: 01/06/2000 **DOB**: 07/08/1942

Outcome: Recovered Causality: Causality probable

Reaction Detai

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

Medicine Details:

 FAMVIR (Other drug)
 Reason:

 500.0
 Milligram
 Daily

 3atch:
 3tarted:
 01/01/1998
 3topped:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 27/05/2000 3topped: 02/06/2000

Laboratory Investigations:

Date	Туре	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.



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

Report Do	etail						
		Seq: 1	Gender: F Weight: Age: DOB:				
	ome: Unknown				ty: Causality possible		
eaction E	Detai						
	eferred Term	Severity	Report Description Treatmer				
Aggression Drug withdr	rawal syndrome			zapine & became verbally eing withdrawn at the time.			
Modicino	Dotaile						
Medicine Details: ZYPREXA (Suspected) Reason:							
·		30	0 Milligram	Daily			
3atc		Started:		Stopped:	CONTIN		
ZOLOFT (Su	uspected)		_				
202011 (00	,	150		son:			
3atc		150. Started:	0 Milligram	son: Daily Stopped:			
3atc Laborato	_{h:} ry Investigat	Started:	0 Milligram	Daily Stopped:	otoile.		
Заtc	:h:	Started:	0 Milligram	Daily Stopped:	Details		



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

Report Do	etail
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Case Number: 154201 Seq: 1 Gender: F
Reported: 26/06/2000 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

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

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report l	Detai∣
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 Case Number:
 154274
 Seq: 1
 Gender:
 F

 Reported:
 28/06/2000
 Weight:
 65.00

Hospitalisation:
Onset Date: 25/05/2000

Age: 35Y

DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

			-
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

3atch: 3tarted: 15/03/2000 3topped: 15/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected)		Reason:					
Tablet	50.0 Milligram	Daily		Oral			
3atch:	Started: 08/06/2000		Stopped:	14/06/2000			
CELEBREX (Suspected)		Reason:	Unspecified a	rthritis			
	400 0 Milliarom	Doily					

400.0 Milligram Daily

3atch: 3tarted: 01/06/2000 3topped: 14/06/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Dental caries		Increase in tooth decay, required 15 filings.	
Dry mouth			

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started: 01/07/1997

Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Dotal		_	
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

3atch: 3tarted: 01/10/1998 3topped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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	у	
3atch:	Started: 08/06/2000		Stopped: 05/07/2000	
ASPIRIN (Suspected)		Reason:	Acute,ill-def cerebrovascular disease w/o hyperte	
	150.0 Milligram	Daily	у	
3atch:	Started: 01/01/1995		Stopped: 05/07/2000	
SERTRALINE HYDROCHLORIDE	(Suspected)	Reason:	Depression	
	50.0 Milligram	Daily	у	
3atch:	Started: 01/06/2000		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Haemoglobin		23/06/2000	159	
	Haemoglobin		05/07/2000	114	
	Other data				Endoscopy showed severe ulcerative duodenitis, with two chronic duodenal ulcers and evidence of recent bleed.

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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

	<u> </u>	<u>-</u>	ā.
Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome			Taking about <25mg to stop symptoms for 1.5 days.
Depersonalisation			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 19/11/1998 3topped: 12/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Smoking marijuana also stops the symptoms.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Sertraline ceased. fluid

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)

Tablet

25.0 Milligram
Daily
Oral

3atch: Started: Stopped: CONTIN

Laborate	aboratory Investigations:							
Date	Туре	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, carbamezepine, paracetamol, digoxin, gliclazide, nystatin, frusemide, isosorbide mononitrate sr, perindopril, spironolactone and omeprazole.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)

Tablet

25.0 Milligram
Daily
Oral

3atch: Started: Stopped: CONTIN

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	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, carbamezepine, paracetamol, digoxin, gliclazide, nystatin, frusemide, isosorbide mononitrate sr, perindopril, spironolactone and omeprazole.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression	
Tablet	25.0 Milligram	Daily		Oral
3atch:	Started: 03/03/2000		Stopped:	07/04/2000

Laboratory Investigations:

Date	Туре	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 vitamine 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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 \$tarted:
 03/03/2000
 \$topped:
 07/04/2000

Laboratory Investigations:

Date	Туре	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 vitamine 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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression	
Tablet	25.0 Milligram	Daily		Oral
3atch:	Started: 03/03/2000		Stopped:	07/04/2000

Laboratory Investigations:

Date	Туре	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 vitamine 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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
Onset Date: 31/03/2000
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 25.0 Milligram
 Daily
 Oral

 3atch:
 Started:
 03/03/2000
 Stopped:
 07/04/2000

Laboratory Investigations:

Date	Туре	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 vitamine 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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)		Reason: D	epression	
Tablet	50.0 Milligram	Daily		Oral
3atch:	Started: 01/09/1999		Stopped:	04/01/2000

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:

Onset Date: 01/01/2000 DOB:
Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/09/1999
 \$topped:
 04/01/2000

Laboratory Investigations:

Date	Туре	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.

Report Run 27/07/200 03:28PN Database: pusime ADRS004 Page 233 of 591



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hypertonia		Stiffness in r leg and weakness	Date of recovery 18/05/00
Dizziness			
Dry mouth			
Malaise			

Medicine Details:

ZOLOFT (Suspected) Reason: Anxiety neurosis

50.0 Milligram Daily

3atch: 3tarted: 15/05/2000 3topped: 16/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had a cva affecting right side in 1995.



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

Report D)etail
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 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 Detai

104011011 20141		-	
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	
3atch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	Depression	
Tablet	0.0		Oral	
3atch:	Started: 10/07/2000		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft ceased, plan to change to meclobemide.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 3topped: 02/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium				128.

Additional Information:

Patient also taking spiractin, senekot, panamax and sorbilax. date of recovery 3.3.00.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Rash		Starting on abdo.	
Pruritus			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 13/07/2000 3topped: 18/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

History: other ssri - nausea.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Gender: F Seq: 1 Reported: 31/07/2000 Weight: 60.00

Hospitalisation: Age: 43

Onset Date: DOB: 03/10/1956 Causality: Causality possible

Outcome: Not yet recovered

Reaction Detai

todotion Botal		E	
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:

Anxiety neurosis **ZOLOFT** (Suspected) Reason: Tablet 50.0 Milligram Daily Oral 3atch: 3tarted: 18/06/1996 28/05/2000 Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Hypertonia		Baby having frequent episodes of leg	
Dyskinesia		Mouth grimacing.	

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 07/06/2000
 3topped:
 13/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Baby 5 mts old. patient breast feeding. after 30 days on zoloft noticed baby having frequent episodes of leg stiffening and mouth grimasing. zoloft was stopped on 13/07/00, baby movements reduced considerably, but didn't completely stopped. recommenced zoloft on 20/07/00, baby movements increased.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Drug level increased			

Medicine Details:

SERTRALINE HYDROCHLORIDE (I	nteraction)	Reason:	Depression	
Oral application 0.0			Oral	
3atch:	3atch: Started:		Stopped:	
CLOZARIL (Interaction)		Reason:	Unspecified schizophrenia	
Tablet	650.0 Milligram	Daily	Oral	
3atch:	3tarted: 01/01/1995		Stopped:	CONTIN

Laboratory Investigations:

	, mreengunemer				
Date	Туре	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.



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

Report [Detail
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 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 Detai

Preferred Term	Severity	Report Description	Treatment
Leukaemia		Lymphoblastic leukaemia	

Medicine Details:

Micarchic Details.				
CLOZARIL (Suspected)		Reason:		
Tablet	300.0 Milligram	Daily	Oral	
3atch:	Started: 02/07/1999		Stopped:	
ZOLOFT (Suspected)		Reason:		
	100.0 Milligram	Daily		
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

		ā.	
Preferred Term	Severity	Report Description	Treatment
Abdominal pain			Metoclopramide 10mg po. required a visit to doctor.
Dizziness			
Headache			
Vomiting			

Medicine Details:

<u>Medicine Details:</u>			
NALTREXONE HYDROCHLORIDE (Susp	ected)	Reason:	
	50.0 Milligram	Daily	
3atch:	Started:	Stopped:	09/08/2000
ZOLOFT (Suspected)		Reason: Depression	
	50.0 Milligram	Daily	
3atch:	3tarted: 09/07/2000	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

H/o alcohol dependency. reaction started within 12 hrs starting naltrexone.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

 italisation:
 Age:
 42Y

Hospitalisation: Age: 4
Onset Date: 15/06/2000 DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Rash erythematous		Rash on legs, face arms.	

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 15/06/2000 3topped: 20/06/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous exposure to zoloft produced same reaction.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal		-	
Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Left side of head pins/needles.	
Rash pustular		Pimples on scalp	Zoloft stopped. required a visit to doctor. date of recovery
Anxiety			
Headache			

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

3atch: 3tarted: 20/07/2000 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking premarin, provera, fgf, sotacor, zantac.



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

Case Num	ber: 156565	Seq:	1		_	ender: F
-	ted: 21/08/200	0			W	/eight: 0.00
ospitalisat						Age: 38
Onset D	ate: 20/07/200	0				DOB : 26/09/1961
	me: Death				Cau	sality: Causality possible
eaction D			<u>, 1</u>		- · · ·	
_	ferred Term	i i	erity	Report I	Description	Treatment
	ne phosphokina	ise inc				
Cardiomega	•					
Orug level ir						
lepatic cirrh	nosis					
Pneumonia						
Sudden dea	th					
M adicina	Dotaile					
/ledicine Mesasal (s			0.0	Reasor	ı:	
	Suspected)	Sta	0.0 arted:	Reasor	ı: Stopped:	
MESASAL (S	Suspected)			Reasor	Stopped:	
MESASAL (S 3atch SERTRALINI	Suspected) n: E HYDROCHLORIC	DE (Suspected)	o.0		itopped:	
MESASAL (S 3atch SERTRALINI 3atch	Suspected) n: E HYDROCHLORIC n:	DE (Suspected)	arted:	Reasor	Stopped:	
MESASAL (S 3atch SERTRALINI	Suspected) n: E HYDROCHLORIC n:	DE (Suspected)	0.0		Stopped:	
MESASAL (S 3atch SERTRALINI 3atch	Suspected) 1: E HYDROCHLORIC 1: Suspected)	DE (Suspected)	o.0	Reasor	Stopped:	
MESASAL (S 3atch SERTRALINI 3atch CALTRATE (Guspected) 1: E HYDROCHLORID 1: Suspected) 1:	DE (Suspected)	0.0 arted: 0.0	Reasor	Stopped: Stopped: Stopped:	
MESASAL (S 3atch SERTRALINI 3atch CALTRATE (Guspected) 1: E HYDROCHLORID 1: Suspected) 1:	DE (Suspected)	0.0 arted: 0.0	Reasor Reasor	Stopped: Stopped: Stopped:	
MESASAL (S 3atch SERTRALINI 3atch CALTRATE (Suspected) 1: E HYDROCHLORID 1: Suspected) 1: (Suspected)	DE (Suspected) Sta	0.0 arted: 0.0 arted:	Reasor Reasor	Stopped: Stopped: Stopped:	
MESASAL (S 3atch SERTRALINI 3atch CALTRATE (3atch RANITIDINE	Suspected) 1: E HYDROCHLORID 1: Suspected) 1: (Suspected)	DE (Suspected) Sta	0.0 arted: 0.0 arted: 0.0 arted:	Reasor Reasor	Stopped: Stopped: Stopped:	
MESASAL (S 3atch SERTRALINI 3atch CALTRATE (3atch RANITIDINE	Suspected) 1: E HYDROCHLORID 1: Suspected) 1: (Suspected)	DE (Suspected) Sta	0.0 arted: 0.0 arted: 0.0 arted:	Reasor Reasor	Stopped: Stopped: Stopped:	Details
MESASAL (S 3atch SERTRALINI 3atch CALTRATE (3atch RANITIDINE 3atch Date 17/12/2002	Suspected) 1: E HYDROCHLORID 1: Suspected) 1: (Suspected) 1: Ty Investigat Type Biochemistry	DE (Suspected) Sta Sta Sta	0.0 arted: 0.0 arted: 0.0 arted:	Reason	Stopped: Stopped: Stopped:	Details
3atch SERTRALINI 3atch CALTRATE (3atch RANITIDINE 3atch Date 17/12/2002 17/12/2002	Suspected) 1: E HYDROCHLORID 1: Suspected) 1: (Suspected) 1: Type Biochemistry Histology	DE (Suspected) Sta Sta Sta	0.0 arted: 0.0 arted: 0.0 arted:	Reason	Stopped: Stopped: Stopped:	Details
MESASAL (S 3atch SERTRALINI 3atch CALTRATE (3atch RANITIDINE 3atch 17/12/2002 17/12/2002 17/12/2002	Suspected) 1: E HYDROCHLORID 1: Suspected) 1: (Suspected) 1: Ty Investigat Type Biochemistry	DE (Suspected) Sta Sta Sta	0.0 arted: 0.0 arted: 0.0 arted:	Reason	Stopped: Stopped: Stopped:	Details



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

Report	Detail
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 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 Detai

				tai		

NITRAZEPAM (Suspected)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
PREDNISONE (Suspected)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
KAPANOL (Suspected)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
	575.0 Milligram	Daily	Oral
Зatch:	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.

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

Seq: 1	Report D	DOB: Causality: escription	: : 45Y	
Severity	Report D	DOB: Causality: escription	Causality probable Treatment	
Severity	Report Do	Causality:	Causality probable Treatment	
Severity	Report D	escription	Treatment	
Severity	Report D			
Seventy	Кероп Б			
		<u> </u> 2010	oπ ceased	
O.O. Milli	₹eason:			
nge Date Tested	Result	Deta	ails	
	\$tarted: 31/07/20	0.0 Milligram 11 t Started: 31/07/2000	0.0 Milligram 1 time Oral Started: 31/07/2000 Stopped: 14/08/200	



Gender: F

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

Report Detail	

Seq: 1

Reported: 21/08/2000 Weight: 51.00 Hospitalisation: Age: 34

Onset Date: DOB: 31/08/1965

Outcome: Recovered Causality: Causality probable

Reaction Detai

Case Number: 156670

teaction Betai		_	
Preferred Term	Severity	Report Description	Treatment
Agitation		Marked agitation.	
Affect lability		Uncontrollable crying.	
Aggression			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 19/04/2000 3topped: 20/04/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Dystonia		Dystonia in lower limbs.	
Confusional state	Severe	Severe confusion	
Hallucination			
Hyperreflexia			
Hypertonia			
Hypotension			
Pyrexia			

Medicine Details:

ZOLOFT (Suspected)			Reason:	Depression	
Tablet	200.0	Milligram	Daily		Oral
3atch:	Started: 01	/03/2000		Stopped:	30/04/2000
TRAMADOL HYDROCHLORIDE (Suspected)			Reason:		
Capsule	400.0	Milligram	Daily		Oral
3atch:	Started: 24	/04/2000		Stopped:	30/04/2000
PERICYAZINE (Suspected)			Reason:		
PERICYAZINE (Suspected)	5.0	Milligram	२eason : Daily		
PERICYAZINE (Suspected) 3atch:	5.0	Milligram		Stopped:	
		Milligram		Stopped:	
3atch:			Daily	Stopped:	

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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 spaciticity required surgical tendon release x 2.
Tremor			

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression	
Tablet	200.0 Milligram	Daily		Oral
3atch:	3tarted: 01/03/2000		Stopped:	30/04/2000
TRAMADOL HYDROCHLORIDE (Suspected	d)	Reason:		
Capsule	400.0 Milligram	Daily		Oral
3atch:	Started: 24/04/2000		Stopped:	30/04/2000
PERICYAZINE (Suspected)		Reason:		
PERICYAZINE (Suspected)	5.0 Milligram	Reason: Daily		
PERICYAZINE (Suspected) 3atch:	5.0 Milligram		3topped:	
, , ,	3 -		Stopped:	
3atch:	3 -	Daily Reason:	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion botal			
Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Date of recovery 27.7.00. required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

Tablet 100.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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 tergretol).



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Malaise			
Nausea			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 23/08/2000
 3topped: 23/08/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking diane 35. reaction to stemetil.



Case Number: 157261 Reported: 01/09/2000 Dispitalisation: Onset Date: 25/08/2000 Outcome: Recovered Detai	Seq: 1		We	nder: U eight: Age: DOB: ality: Causality probable
Preferred Term culogyration	Severity	Report Do	escription	Treatment
ledicine Details: ZOLOFT (Suspected)		Reason:	Anxiety neurosis	
Tablet	50.0	Milligram Da	ily Ora	I
aboratory Investigation	e.			
	Range Date Te	sted Result		Details



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botai		_	<u> - </u>
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

3atch: 3tarted: 21/08/2000 3topped: 26/08/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking provera and amoxycillin.



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

Report Detail	Re	ро	rt C	Deta	il
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Case Number:157502Seq:1Gender:MReported:06/09/2000Weight:Hospitalisation:Admitted to hospitalAge:67

Onset Date: 18/08/2000 DOB: 22/10/1932

Outcome: Recovered Causality: Causality possible

Reaction Detai

Cuction Betai			
Preferred Term	Severity	Report Description	Treatment
Dizziness			Patient hospitalised. date of recovery 24/08/00. zoloft ceased. fluid restrict ed.
Hyponatraemia			
Inappropriate antidiuretic hormon			
Nausea			

	Detai	

modification bottom				
ZOLOFT (Suspected)	Reason:			
	0.0			
3atch:	Started:	Stopped:		

Laboratory Investigations:

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Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104041011 20441			-
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft ceased. given demeclocycline 150mg qid 3.7.00. date of recovery

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 03/08/2000
 3topped:
 09/08/2000

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Movement disorder.		

Medicine Details:

ZOLOFT (Suspected) Reason: Anxiety neurosis

150.0 Milligram Daily

3atch: 3tarted: 01/09/1996 3topped: 24/12/1996

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal			
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	Daily Oral		Oral		
Зatch:	3tarted: 05/06/2000		Stopped:	12/08/2000	
SERTRALINE HYDROCHLORIDE (S	uspected)	Reason:			
Oral application	25.0 Milligram	Daily		Oral	

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal									
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

3atch: 3tarted: 03/07/2000 3topped: 16/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 18/7/00.



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

Report Detail

Case Number:157945Seq:1Gender:FReported:20/09/2000Weight:80.00Hospitalisation:Admitted to hospitalAge:59Y

Onset Date: 14/07/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Botai			
Preferred Term	Severity	Report Description	Treatment
Anxiety			
Arrhythmia			
Confusional state			
Diarrhoea			
Palpitations			Observation and tx in hospital.
Serotonin syndrome			

Medicine Details:

3atch:

 ZOLOFT (Interaction)

 Reason:

 50.0 Milligram
 Daily

 3atch: Started: Started: Stopped:

 HYPERICUM-ST JOHN'S WORT (Interaction)
 Reason: Anxiety neurosis

 2.0 Dose Unspecified
 Daily

Started: 22/06/2000 **Stopped**: 14/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking isoptin, menorest, gastrostop, zinc chelate. long history of wolff-parkinsons white syndrome.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Arthralgia			
Diarrhoea			
Pruritus			
Rash follicular			Required a visit to doctor

Medicine Details:

Medicine Details.					
OESTRADIOL IMPLANT (Suspected)		Reason:	Menopausal sy	mptoms	
	0.0				
Зatch:	Started:		Stopped:		CONTIN
ZOLOFT (Suspected)		Reason:			
	50.0 Milligram	Daily	y		
3atch:	Started: 01/06/2000		Stopped:	28/09/2000	

Laboratory Investigations:

Date	Туре	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.

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

Report D	etai
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 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 Detai

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

 3atch:
 3tarted:
 11/09/2000
 \$topped:
 14/09/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



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

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 Detai

Preferred Term	Severity	Report Description	Treatment
Diarrhoea			Date of recovery 30.9.00.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 04/08/2000 **3topped:** 15/09/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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.

Reported: 09/10/2000 Weight: 60.00 Hospitalisation: Age: 28Y

Onset Date: 16/08/2000 DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

toaction Dotal		E	
Preferred Term	Severity	Report Description	Treatment
Therapeutic response unexpecte		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

3atch: 3tarted: 10/07/2000 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking monofeme.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Caction Detai		-	
Preferred Term	Severity	Report Description	Treatment
Tremor		Shaking hands.	
Headache			
Nausea			

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

50.0 Milligram 1 time

3atch: 3tarted: 11/07/2000 3topped: 11/07/2000

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Caction Detai	-	_	
Preferred Term	Severity	Report Description	Treatment
Gastritis		Antral gastritis	
Weight decreased		Weight loss from 50kg to 45kg.	
Dysphagia			
Oesophageal stenosis			

Medicine Details:

CELEBREX (Suspected)		Reason:	
Capsule	0.0		Oral
3atch:	Started:	Stopped:	CONTIN
ROCALTROL (Suspected)		Reason:	
Capsule	0.0		Oral
3atch:	Started:	Stopped:	CONTIN
ZOLOFT (Suspected)		Reason:	
Tablet	0.0		Oral
3atch:	Started:	Stopped:	CONTIN
FOSAMAX (Suspected)		Reason: Osteoporosis	s
Tablet	10.0 Milligram	Daily	Oral
3atch:	Started: 01/01/1998	Stopped:	28/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Radiololgy				Endoscopy - a barium meal swallow showed a long narrow stricture of the proximal esophagus. antral gastritis tested

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.

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Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Date Type	Range	Date Tested	Result		Deta	alls		
Laboratory Investigatio	ons:							
3atch:	Star	ted:		:	topped:			
Tablet		gram	Daily	Oral				
Medicine Details: ZOLOFT (Suspected)			Reas	on:				
mary moonandines					-			
Faecal incontinence Jrinary incontinence								
Preferred Term	Seve	erity	Repor	t Descript	ion	Treatment		
Outcome: Unknown eaction Detai					Causality	: Causality poss	ible	
Onset Date:			DOB:					
ospitalisation:					Weight:	: : 09Y		
Reported: 23/10/2000								



Report De	tail						
Report Hospitalisati		Seq: 1				Weiç A	ge: 50Y
Onset Da	ate: ne: Recovere	d					OB: ity: Causality possible
eaction D		u				Causai	ity. Causality possible
	erred Term	Sever	ity	Report	Description		Treatment
Diarrhoea		Severe	Seve	re bowel prob	lems for 3 month	ns.	Zoloft ceased.
Medicine l				Reaso	n·		
Table			50.0 Milli		Daily	Oral	
3atch	:	Start	ed:		Stopped:		
	y Investigat			· 1			
Laborator Date	y Investigat		Date Tested	Result			Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 158741	Seq:	1		Gend	der: F	
Reported: 23/10/20	_			Weig		
Hospitalisation:				Α	.ge:	
Onset Date:				D	OB:	
Outcome: Unknow	n			Causa	lity: Causality poss	ible
eaction Detai				-		
Preferred Term	Sev	erity	Repor	t Description	Treatment	
Visual disturbance		Visu	ıal disturbance	e and then a headache.		
Migraine						
Marina Brazilia						
Medicine Details: ZOLOFT (Suspected)			Reas	on:		
Tablet		0.0	1603	Oral		
Satch:	Sta	arted:		Stopped:		
				, roppos.		
Laboratory Investiga	ations:					
Laboratory Investiga Date Type	Range	Date Tested	Result		Details	
Additional Information	on:					
eport Run 27/07/200 03:28F	PN Database: pu	usime	Δ	DRS004	Page 269	of 591
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Cough			Zoloft ceased. required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) Reason: Anxiety neurosis

50.0 Milligram Daily

3atch: 3tarted: 16/11/1999 3topped: 06/10/2000

Laboratory Investigations:

Date	Туре	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.



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

Report [Detail
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 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 Detai

reaction Detai	-		
Preferred Term	Severity	Report Description	Treatment
Convulsion			Zoloft reduced to 100mg. sodium valproate given.

Medicine Details:

Modifile Botalie.			
ZOLOFT (Suspected)		Reason:	
Tablet	0.0	Oral	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No history of convulsions.



Report Detail

Case Number: 158769

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Reported	23/10/2000 Weight:								
In the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the				Age: 30Y					
							DOB:		
						Cau	u sality: Ca	ausality poss	ible
action Deta							Ī		
Preferr	red Term	Sev	erity	Repor	t Desci	ription		Treatment	
elirium							Zoloft c	eased. antipsy	chotic
aranoia									
sychotic disor	der								
edicine De									
ZOLOFT (Suspe	cted)			Reas					
Tablet			400.0 Milli	gram	Daily		ral		
3atch:		3ta	irted:			Stopped:			
aboratory I	nvestigat	ions:							
Date	Type	Range	Date Tested	Result			Details		
dditional Ir	nformatio	n:							
ort Run 27/07/2	00 03:28PN	Database: pu	ısime	A	DRS004	1		Page 272	of 591
		r						90	2. 301



Report Detail						
Case Number: 158809 Reported: 23/10/20 pspitalisation:	Seq:	1			Gender: U Weight: Age:	
Onset Date:					DOB:	
Outcome: Unknow	n			C	Causality: C	ausality possible
Preferred Term	Seve	eritv	Repor	t Description		Treatment
sthenia		•		ess in her legs.		
lypoaesthesia				fingers and toes in	last 18	
ledicine Details: ZOLOFT (Suspected)			Reas	on:		
Tablet		100.0 Milli	igram	Daily	Oral	
3atch:	3ta	rted:		Stopped:		
_aboratory Investiga						
Date Type	Range	Date Tested	Result		Details	
Additional Information	on:					
port Run 27/07/200 03:28F	PN Database: pu	sime	Δ	.DRS004		Page 273 of 591



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			Zoloft ceased

Medicine Details:

3atch:

LAMICTAL (Interaction) Reason: Other&unspecified epilepsy

3tarted: 20/09/1997

400.0 Milligram Daily

Stopped:

ZOLOFT (Interaction) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 14/04/2000 **3topped:** 28/06/2000

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100000000000000000000000000000000000000			
Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Giddiness, a sense of inbalance.	
Agitation	Severe	Severe agitation.	
Hyperhidrosis			
Vomiting			Date of recovery 27/10/2000.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 23/10/2000 3topped: 26/10/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - doxyhexal.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Mind racing	
Drug ineffective		No change in depression.	
Speech disorder		Talking rapidly	
Agitation		Unsettled jittery	Diazepam 5mg. advised to cease zoloft.
Headache			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 23/10/2000 3topped: 31/10/2000

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome			Patient was transferred to

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 100.0 Milligram Daily Oral

3atch: 3tarted: 16/05/2000 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

3atch: **3tarted**: 01/11/1999 **3topped**:

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Multiple congenital abnormalities		Child was born with a deformity (type	

Medicine Details:

ZOLOFT (Suspected)

Tablet

100.0 Milligram
Daily
Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Prothrombin level decreased			

Medicine Details:

Micaicine Details.						
SERTRALINE HYDROCHLORIDE (Inter	action)		Reason:			
	25.0	Milligram	Daily			
3atch:	Started: 30)/05/2000		Stopped:		
WARFARIN SODIUM (Interaction)			Reason:			
Tablet	5.0	Milligram	Daily	C)ral	
3atch:	Started:		L TERM	Stopped:		
SERTRALINE HYDROCHLORIDE (Inter	action)		Reason:			
	50.0	Milligram	Daily			
Batch:	Started: 06	3/07/2000		Stonned:		

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: 3tarted: 20/10/2000 3topped: 30/10/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zoloft therapy was taken at 25mg/daily then increased to 50mg/daily. patient also taking - ferrograd c.



Report Detail Case Number: 159522 Reported: 24/11/2000 Dispitalisation: Admitted to hosp Onset Date: Outcome: Recovered Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Term Detail Preferred Te	Severity		eport Descripti	Cau	ender: F /eight: Age: 20Y DOB: sality: Causality Treati Patient was hos ceased.	ment
Reported: 24/11/2000 spitalisation: Admitted to hosp Onset Date: Outcome: Recovered action Detai Preferred Term erotonin syndrome edicine Details: COLOFT (Suspected)	Severity 25.0		Reason:	Cau	Veight: Age: 20Y DOB: sality: Causality Treati	ment
Spitalisation: Admitted to hosp Onset Date: Outcome: Recovered Interest Term Preferred Term Protonin syndrome Addicine Details: OLOFT (Suspected)	Severity		Reason:	Cau	Age: 20Y DOB: sality: Causality Treati	ment
Onset Date: Outcome: Recovered Inction Detai Preferred Term Inctionin syndrome Pedicine Details: DLOFT (Suspected)	Severity		Reason:	ion	DOB: sality: Causality Treati Patient was hos	ment
Outcome: Recovered ction Detai Preferred Term rotonin syndrome edicine Details: DLOFT (Suspected)	25.0		Reason:	ion	Treate Patient was hos	ment
Preferred Term rotonin syndrome edicine Details: DLOFT (Suspected)	25.0		Reason:	ion	Treati	ment
Preferred Term rotonin syndrome edicine Details: DLOFT (Suspected)	25.0		Reason:		Patient was hos	
edicine Details: OLOFT (Suspected)			Total	topped:	Patient was hos ceased.	pitalised. zolo
DLOFT (Suspected)			Total	topped:		
OLOFT (Suspected)			Total	topped:		
3atch:) Milligram		topped:		
3atch:	Started:		<u> </u>	topped:		
aboratory Investigations: Date Type Rai	ange Date Te	ested Resul	lt		Details	



eport Detail	4=0=0=	_					
Case Number:		Seq: 1				Gender: M	
-	24/11/2000		Weight:				
ospitalisation:						Age: 37Y	
Onset Date:						DOB:	
Outcome:					Са	usality: Causality probable	
action Detai		Cavar	:4	Danam	- Decembries	Treatment	
Preferre	a rerm	Sever			Description	Treatment	
hills			Shak	king			
gitation							
onstipation							
ry mouth							
allucination							
ypertonia							
edicine Deta				3000	nn: Dorrossion		
ZOLOFT (Suspecte	ed)		50.0 M:U	Reas	·		
3atch:		Mant	50.0 Milli ed: 20/10/2		Daily Stopped:	23/10/2000	
aboratory In			Data Tantad	Decult		Detaile	
Date	Туре	Range [Date Tested	Result		Details	
dditional Inf	ormation:						



_	ber: 159578 ted: 29/11/2000	Seq: 1		Wei	der: M ght: 72.00			
ospitalisat					.ge : 37Y			
	ate: 22/10/2000			OB:				
	me: Recovered			lity: Causality probable				
eaction D		Coverity	Depart D		Tractment			
	ferred Term	Severity	Report Do	-	Treatment			
'isual distur	bance		Saw stationary object					
lypertonia			Tighting of muscles in	arms.				
gitation Constipation								
onsupation Ory mouth	I							
lallucination	า							
ledicine			N	Depression				
ZOLOFT (Su			Reason:	Depression				
Table 3atch			50.0 Milligram Daily Oral Started: 20/10/2000 Stopped: 23/10/2000					
	y Investigatio		Tested Result		Details			
_aborator Date	'y Investigati Type		Tested Result		Details			



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 01/06/2000 3topped: 28/11/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Report D	etail						
	nber: 159808	Seq: 1					der: F
Repoi lospitalisa	rted: 08/12/200	00				Weig A	ge: 50Y
Onset D							OB:
	ome: Unknown						ity: Causality possible
eaction E	Detai						
	eferred Term	Severit		•	Description		Treatment
Neurosis			Kicki	ng legs about	in the air.	,	Valium to sedate the patient.
Medicine ZOLOFT (Su				Reaso	n:		
Tabl			50.0 Milli		Daily	Oral	
3atc	h:	Starte	d:		Stoppe	ed:	
	ry Investigat						
Laborato Date	ry Investigat		ate Tested	Result			Details



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

Case Number: 159811 Seq: 1 Gender: F
Reported: 08/12/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

todotion Dotal		_	<u> </u>
Preferred Term	Severity	Report Description	Treatment
Haemorrhage		Bleeding	
Purpura			Zoloft was ceased and recommenced 5 months later.

Medicine Details:

ZOLOFT (Suspected)		Reason:			
Tablet	50.0	Milligram	Daily	Oral	
3atch:	Started:		3to	pped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Pateint experienced symptoms after 3 months of therapy with zoloft.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

eaction Detai					
Preferred Term	Severity	Report Description	Treatment		
Drug withdrawal syndrome					
Headache			Required a visit to doctor.		
Nausea					

Medicine Details:

Medicine Details.			
CELEBREX (Suspected)		Reason: Pain	
Capsule	200.0 Milligram	Daily	Oral
3atch:	3tarted: 01/09/2000	Stopped:	29/11/2000
ZOLOFT (Suspected)		Reason: Depression	
	50.0 Milligram	Daily	
3atch:	Started: 24/11/2000	Stopped:	04/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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	
	0.0			
3atch:	Started:		Stopped:	
FERRO-GRADUMET (Other drug)		Reason:		
	0.0			
3atch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	Depression	
	1.0	Dose Unspecified 1 tim	ne	
3atch:	Started: 19/	10/2000	Stopped: 19/10/2000	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

No previous seizure-type episodes. no known drug allergies. patient has alzheimer's disease.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104011011 20141		-	
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

3atch: 3tarted: 17/05/2000 3topped: 27/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

After taking zoloft for 10 days patient experienced severe symptoms.



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

Report Detail	Re	ро	rt C	Deta	il
---------------	----	----	------	-------------	----

 Case Number:
 159903
 Seq: 1
 Gender:
 F

 Reported:
 11/12/2000
 Weight:

Hospitalisation: Admitted to hospital
Onset Date: 19/05/2000
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Dotai		<u> - </u>		
Preferred Term Severity		Report Description	Treatment	
Atrial fibrillation			Patient admitted to emergency department.	

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

3atch: Started: 14/04/2000 Stopped: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

		-	
Preferred Term	Severity	Report Description	Treatment
Coordination abnormal			
Dizziness			Patient was hospitalised.

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/09/2000
 3topped:

Laboratory Investigations:

Date	Туре	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.



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

Re	po	rt	D	et	ai	
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Case Number: 159960 Seq: 1 Gender: M
Reported: 13/12/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

todotion Botal			
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
3atch:	Started:		Sto	opped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking - amiodorine. relevant history - atrial fibrillation and prostatism.



Report De	tail									
	oer: 159965 ed: 13/12/200 on:	Seq: 1					Gender: Weight: Age:			
	ate: 22/05/200 me: Unknown	0	DOB: Causality: Causality possibl						۵	
eaction De						•	ausanty.	Oausani	y possible	•
	ferred Term	Severity		Repor	t Descri	ption		Trea	atment	
Dizziness										
Medicine l										
ZOLOFT (Sus		-	O MULTURA	Reas			01			
Table 3atch).0 Milligra 18/05/2000		Daily	Stopped:	Oral 22/05/200	0 CONT	TINI	
_aborator	y Investigat	ions:								
Date	Туре	Range Date	Tested	Result			Deta	ails		
Additiona	l Informatio	n:	,							
07/0	7,000 00 00 00 00				DDOOA					



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Nocturnal enuresis.	

Medicine Details:

ZOLOFT (Suspected) Reason:

 Tablet
 100.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 01/11/1999
 3topped:
 28/02/2000

Laboratory Investigations:

Date	Туре	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.

Report Run 27/07/200 03:28PN Database: pusime ADRS004 Page 295 of 591



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 159970	Seq: 1	Gender: M					
Reported: 14/12/200	Veight:						
ospitalisation:				Age: 45Y			
Onset Date:				DOB:			
Outcome: Not yet re	covered		Ca	usality: Causality possible			
eaction Detai		_					
Preferred Term	Severity	Repo	t Description	Treatment			
Nausea		Nausea when he	yawns.				
Bruxism							
Drug ineffective							
Ejaculation failure							
Medicine Details:							
ZOLOFT (Suspected)		Reas					
3atch:	50.0 Started:) Milligram	Daily Stopped:				
Laboratory Investigat	t ions: Range Date Te	ested Result		Details			
Additional Informatio	n:						
port Run 27/07/200 03:28PN	Database: pusime		ADRS004	Page 296 of 591			



Report Det	ail								
ospitalisatio	ed: 14/12/200 on:	Seq:	1	Gender: F Weight: Age: 60Y					
Onset Dat Outcom	te: ıe: Recovere	d				DOB: ality: Causality possible			
action De						·			
Prefe	erred Term	Seve	erity	Repor	t Description	Treatment			
sturbance ir	attention								
edicine D				Reas	on: Depression				
OLOFT (Susp Tablet	ectea)		100.0 Milli	ıl					
3atch:		Star	rted:	II					
ala aratam	Investigat	iono							
Date	Investigat Type	Range	Date Tested	Result		Details			
	,,	Ů				_			
dditional	Informatio	n:							
ort Run 27/07	7/200 03:28PN	Database: pus	sime	Δ	.DRS004	Page 297 of 591			



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Persistent watery diarrhoea	Zoloft ceased

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 19/09/2000 3topped: 02/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking depo-provera, polaramine.



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

Report D)etail
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 Case Number:
 159993
 Seq: 1
 Gender:
 F

 Reported:
 08/12/2000
 Weight:

 Hospitalisation:
 Age: AD

Onset Date: DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hypotonia neonatal		Baby born "floppy".	

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Dysphagia		Swallowing movements when asleep on reduced dose.	

Medicine Details:

ZOLOFT (Suspected)

Tablet

100.0 Milligram

Daily

Oral

3atch:

\$tarted: 01/06/1999

\$topped:

Laboratory Investigations:

Date	Туре	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.



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

Report Detail	Re	ро	rt C	Deta	il
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 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 Detai

todotion Botal		<u>-</u>	
Preferred Term	Severity	Report Description	Treatment
Pyrexia		High temperature	
Confusional state			
Convulsion			
Hyperreflexia			
Hypertonia			

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 200.0 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 27/04/2000
 \$topped:
 01/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking tramodol, neulactil, florinef.



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

Case Number:160102Seq:1Gender:FReported:14/12/2000Weight:Hospitalisation:Admitted to hospitalAge:90Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

П	eaction Detai	_		
	Preferred Term	Severity	Report Description	Treatment
	Diarrhoea			Patient was admitted to hospitalised. zoloft was
	Serotonin syndrome			
	Tremor			

Medicine Details:

Medicine Details.					
HYPERICUM-ST JOHN'S WORT (Interaction)		Reason:		
Tablet	0.0			Oral	
3atch:	Started:		3	topped:	
ZOLOFT (Interaction)			Reason:		
Tablet	50.0	Milligram	Daily	Oral	
3atch:	Started:		3	topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking celebrex, panadol, valium.



Causality: Causality possible

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

Report Detail	Re	ро	rt C	Deta	il
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Case Number:160115Seq:1Gender:FReported:20/12/2000Weight:Hospitalisation:Admitted to hospitalAge:

Onset Date: 06/12/2000 DOB:

Outcome: Not yet recovered

Reaction Detai

todotion botal			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Cessation of zoloft and fluid restriction. patient was

Medicine Details:

ZOLOFT (Suspected)		Reason:	
	0.0		
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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

Additional Information:

Patient was also taking tritace, astrix, pravachol.



Case Number: 160150

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: M

Reported: 21/12/2000		Weight:				
spitalisation:			Age:			
Onset Date:			DOB:			
Outcome: Not yet red	covered		Causality: Causality possible			
action Detai		•				
Preferred Term	Severity	Report D	escription		Treatment	
sual disturbance		Dimmed vision.				
pertonia		Felt stiff.				
ıraesthesia		Tingling sensation in	arms.			
y mouth						
/spnoea						
atigue						
alpitations						
edicine Details: ZOLOFT (Suspected) Tablet	100.0	Reason: O Milligram Da		ral		
3atch:	Started:	-	Stopped:			
aboratory Investigati						
aboratory Investigati	Ons: Range Date Te	ested Result		Details		
		ested Result		Details		
		ested Result		Details		
		ested Result		Details		
Date Type	Range Date Te	ested Result		Details		
	Range Date Te	ested Result		Details		
Date Type	Range Date Te	ested Result		Details		



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

Report	Detai∣
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Case Number: 160152 Seq: 1 Gender: M
Reported: 21/12/2000 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Caction Detai		-	
Preferred Term	Severity	Report Description	Treatment
Alcohol intolerance			
Drug level increased			

Medicine Details:

ZOLOFT (Interaction)		Reason:	
Tablet	0.0	Oral	
3atch:	Started:	Stopped:	
ALCOHOL (Interaction)		Reason:	
Oral application	0.0	Oral	
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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**

Case Number: 160153 Reported: 21/12/2000	Seq: 1		Gender: M Weight:			
lospitalisation:				Age: 65Y		
Onset Date: Outcome: Recovered			Cau	DOB: sality: Causality possible		
eaction Detai			Cau	sailty. Causality possible		
Preferred Term	Severity	Repo	ort Description	Treatment		
Hyperglycaemia		After 2d blood su	gar level significantly	Doctor disontinued the zoloft and patient returned to normal.		
Diabetes mellitus				and patient retained to normal.		
Medicine Details: ZOLOFT (Suspected)		₹ea	son:	1		
Tablet	50.0) Milligram	Daily Or	al		
3atch:	Started:		Stopped:			
Laboratory Investigatio	ns: Range Date Te	ested Result		Details		
Additional Information:						
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

104011011 20141		-	
Preferred Term	Severity	Report Description	Treatment
Epistaxis		Could last up to 30 minutes.	

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

3atch: Started: 01/05/2000 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
Onset Date:

OB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

10404011 20141		-	=
Preferred Term	Severity	Report Description	Treatment
Infertility female			

Medicine Details:

ZOLOFT (Suspected)	Reason:				
Tablet	100.0 Milligram	Daily	Oral		
3atch:	Started:	3top	ped:	3Y	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient commenced zoloft 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**

Case Number: 160169 Reported: 21/12/200	Seq:	1				nder: F ight:	
lospitalisation:	O .					Age:	
Onset Date:						OOB:	
Outcome: Not yet re	covered					ality: Causality poss	ible
eaction Detai						•	
Preferred Term	Seve	rity	Repor	t Descrip	otion	Treatment	
Anxiety						Diazepam helped receffects within 15 min	luce side of dosing.
Medicine Details:							
ZOLOFT (Suspected)		OF O Milli	Reas		Oral		
Tablet 3atch:	Star	25.0 Milli	gram	Daily	Oral Stopped:		
Laboratory Investigat	ions:						
Date Type	Range	Date Tested	Result			Details	
Additional Information	ո։						
eport Run 27/07/200 03:28PN	Database: pus	sime	Α	DRS004		Page 309	of 591



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number:	160170	Seq:	1			Gende	er: F	
Reported:	21/12/200	_				Weigh	nt:	
Hospitalisation:						Ag	e: 20Y	
Onset Date:						DO	B:	
Outcome:	Unknown					Causalit	y: Causality possi	ible
Reaction Deta	i							
Preferre	ed Term	Seve	erity	Repor	Description		Treatment	
Purpura								
Medicine Des		DE (Suspected)		₹eas				
Tablet			50.0 Milli	gram	Daily	Oral		
3atch:		Sta	rted:		Stopped	:		
Laboratory li	nvestigat	ions:						
Date	Туре	Range	Date Tested	Result		D	etails	
Additional In	formatio	n:						
eport Run 27/07/20	0 03:29PN	Database: pu	sime	A	DRS004		Page 310	of 591



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

Report D	etai
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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 Detai

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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking aspirin.



	er: 160172	Seq:	1			Gender: I	F
_	ed: 21/12/2000)	Weight:				
spitalisati				Age: 30Y DOB:			
Onset Da					0		
	ne: Unknown				Causality possible		
action De	erred Term	Seve	rity	Renor	t Description		Treatment
raesthesia		0000	_	and needles			rreatment
					<u> </u>	l	
	D - 4 - 11 -						
edicine [OLOFT (Sus	Details:			Reas	on:		
Tablet			50.0 Milli		Daily	Oral	
3atch:		Star	rted:	gram	Stopped:		
borator	v Investigati	ons:					
borator y	y Investigati _{Type}	ons: Range	Date Tested	Result		Details	3
			Date Tested	Result		Details	3
			Date Tested	Result		Details	3
			Date Tested	Result		Details	3
			Date Tested	Result		Details)
			Date Tested	Result		Details	S
			Date Tested	Result		Details	3
Date	Туре	Range	Date Tested	Result		Details	3
Date		Range	Date Tested	Result		Details	3
Date	Туре	Range	Date Tested	Result		Details	
Date	Туре	Range	Date Tested	Result		Details	3
Date	Туре	Range	Date Tested	Result		Details	3



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160173 Reported: 21/12/2000	Seq: 1			Gender: F Weight:
lospitalisation: Onset Date:				Age: 80Y DOB:
Onset Date: Outcome: Recovered			Ca	usality: Causality possible
eaction Detai			Ca	usanty. Causanty possible
Preferred Term	Severity	Repo	rt Description	Treatment
Nausea				Zoloft was ceased and patient improved within 24 hrs.
Medicine Details: ZOLOFT (Suspected)		₹eas	son:	
Tablet	50.0	Milligram		Oral
3atch:	Started:	g	Stopped:	
_aboratory Investigatio	ons:			
Date Type	Range Date Te	sted Result		Details
Additional Information	:			
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160174 Reported: 21/12/2006 Hospitalisation: Onset Date: Outcome: Not yet red		Gender: F Weight: Age: DOB: Causality: Causality pos			
eaction Detai		 			
Preferred Term	Severity		t Description	Treatment	
Weight increased		Weight gain withir	9-10 months of use.		
Medicine Details: ZOLOFT (Suspected)		Reas	on.		
Tablet	0.0		Oral		
Batch:	Started:		Stopped:		
Laboratory Investigati	ions:				
Date Type	Range Date Te	ested Result		Details	
Additional Information	<u> </u>		ı		
eport Run 27/07/200 03:29PN	Database: pusime	Α	DRS004	Page 314 of 591	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

teaction Betai	-		
Preferred Term Severity		Report Description	Treatment
Muscle twitching		"little fits in the brain".	
Palpitations			Condition is managed with inderal and rivotril. zoloft

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started:

L TERM

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Neurologist diagnosed tourette's-like condition induced by zoloft.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100.01.01.2010.		-	
Preferred Term	Severity	Report Description	Treatment
Convulsion		Muscle twitching and jerking whilst asleep.	
Insomnia			
Libido decreased			

Medicine Details:

Medicine Details.					
TEMAZEPAM (Suspected)			Reason:		
Oral application	0.0		Oral		
3atch:	Started:		3	topped:	
ZOLOFT (Suspected)			Reason:		
Tablet	100.0	Milligram	Daily	Oral	
3atch:	Started:		3	topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Zoloft was increased to 100mg 6 weeks ago.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

 3atch:
 3tarted:
 29/05/2000
 3topped:
 30/05/2000

Laboratory Investigations:

Date	Туре	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**

Case Number: 160211 Reported: 22/12/2000	Seq: 1				Gende	r: M	
Nepolieu. 22/12/2000					Weigh		
lospitalisation:					Ag	e: 73Y	
Onset Date:					DO		
Outcome: Recovered				Causality: Causality possible			
eaction Detai					1		
Preferred Term	Severity	'	Repor	t Descriptio	on	Treatment	
Hallucination							
Tremor							
Medicine Details:							
ZOLOFT (Suspected)			Reas	on:			
Tablet		50.0 Millio	gram	Daily	Oral		
3atch:	Started	:		3to	ppped:		
aboratory Investigation		te Tested	Result	Ι	De	etails	



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Reported: 22/12 ospitalisation: Onset Date: Outcome: Unkneraction Detai Preferred Terrorepression	own	verity Decre	Report Does an ease in mood an	escription	Weight: Age: DOB: ausality:	Causality possible Treatment
Onset Date: Outcome: Unknoteaction Detai Preferred Terr				escription	DOB:	
Outcome: Unkn eaction Detai Preferred Terr				escription		
eaction Detai Preferred Terr				escription	ausality:	
Preferred Terr	n Sev					Treatment
	m Sev					Treatment
epression		Decre	ease in mood an	d teariness.		
ledicine Details:						
ZOLOFT (Interaction)			Reason:			
Tablet		0.0			Oral	
3atch:	3t	arted:		Stopped:		
FLAGYL (Interaction)			Reason:			
Tablet		0.0			Oral	
3atch:	3t	arted:	STERM	Stopped:		
AMOXYCILLIN TRIHYDRA	ATE (Interaction)		Reason:			
Oral application		0.0			Oral	
3atch:	3t	arted:		Stopped:		
aboratory Invest	igations:					
Date Type	Range	Date Tested	Result		Detai	ls



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160213	Seq: 1		G	Gender: F			
Reported: 22/12/2000	•			Weight:			
ospitalisation:				Age: 64Y			
Onset Date:			DOB:				
Outcome: Unknown			Causality: Causality possible				
eaction Detai							
Preferred Term	Severity	Repor	t Description	Treatment			
-atigue		Increasing exhaus	tion.				
Hypertension							
Hyponatraemia				Zoloft decreased.			
Medicine Details: ZOLOFT (Suspected)		Reas	on:				
Tablet	0.0	(eas		Oral			
3atch:	Started:		Stopped:	51 Cl			
aboratory Investigatio	ns: Range Date Tes	sted Result		Details			
Турс	range Bate rea	result		Botalio			
Additional Information:							
oort Run 27/07/200 03:29PN	Database: pusime	A	DRS004	Page 320 of 591			



	ail				
Case Numbe	er: 160215	Seq: 1		G	ender: F
	ed: 22/12/2000			V	Veight:
ospitalisatio					Age: 58Y
	te: 01/07/2000				DOB:
	ne: Not yet recove	red		Cau	usality: Causality possible
eaction De		1 0 " 1			
	erred Term	Severity		t Description	Treatment
Blaucoma		ļ ļ	Early glaucoma.		
/ledicine D ZOLOFT (Susp			Reas	son:	
Tablet		100.0	Milligram	Daily C)ral
3atch:		Started:		Stopped:	
ahoratory	, Investigations				
L aboratory	' Investigations Type F	tange Date Tes	sted Result		Details



Additional Information:

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

Repor ospitalisat Onset D		Seq:	1	Gende Weigh Ago DOE			nt: e: 67Y 3:	
	ome: Unknown			Causality: Causality possible				
eaction D			.,		D : "	1	- , ,	
	eferred Term	Seve	erity	кероп	Description		Treatment	
Dizziness								
lausea	undrama							
Serotonin sy Tremor	ynarome							
		•	•					
	Details:							
CALTRATE ((Other drug)			Reason	n:			
Table	et		0.0		(Oral		
3atch	h:	3ta	rted:		Stopped:			
				Reasor	n:			
FOLIC ACID	(Other drug)				·			
FOLIC ACID Table			0.0			Oral		
	et	Sta	0.0			Oral		
Table	et h:	Sta		Reason	Stopped:	Oral		
Table 3atch	et h: Other drug)	Sta			Stopped:	Oral Oral		
Table 3atch STEMETIL (C	et h: Other drug) et		rted:		Stopped:			
Table 3atch STEMETIL (C Table 3atch	et h: Other drug) et h:		o.0		Stopped: n: Stopped:			
Table 3atch STEMETIL (C Table 3atch	et h: Other drug) et h: (Other drug)		0.0	Reason	Stopped: Stopped:	Oral		
Table 3atch STEMETIL (C Table 3atch PREMARIN (et h: Other drug) et h: (Other drug)	Sta	0.0 rted: 0.0	Reason	Stopped: Stopped: Stopped:			
Table 3atch STEMETIL (C Table 3atch PREMARIN (et h: Other drug) et h: (Other drug)	Sta	0.0	Reason	Stopped: Stopped:	Oral		
Table 3atch STEMETIL (C Table 3atch PREMARIN (Table 3atch	et h: Other drug) et h: (Other drug) et	3tai 3tai	0.0 rted: 0.0	Reason	Stopped: Stopped: Stopped:	Oral		
Table 3atch STEMETIL (C Table 3atch PREMARIN (Table 3atch	et h: Other drug) et h: (Other drug) et h: et	3tai 3tai	0.0 rted: 0.0	Reason	Stopped: Stopped: Stopped:	Oral	ls	

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: Reported: Hospitalisation: Onset Date: Outcome:	22/12/2000	Seq: 1			C	Gender: Weight: Age: DOB:	
eaction Detai					C	ausanty.	Causality possible
eaction Detai							
Medicine Deta				Reason:			
Tablet	ea)	50.0	Milligram	Daily		Oral	
3atch:		Started:	wiiiigram	Dally	Stopped:	Olai	
CELEBREX (Susp	ected)	Jui tou.		Reason:	Osteoarthritis		
Capsule	·	200.0	Milligram	Daily		Oral	
3atch:		Started:			Stopped:		
Laboratory In	vestigations:						
Additional Int	formation:						

Patient had been taking zoloft 50mg which was later increased to 100mg, two to three weeks later the patient was commenced on



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160232	Seq: 1			Gender: F		
Reported: 22/12/2000	•			Weight:		
lospitalisation:				Age:		
Onset Date:				DOB:		
Outcome: Not yet red	covered		Ca	usality: Causality possible		
eaction Detai	· · · · · · · · · · · · · · · · · · ·					
Preferred Term	Severity	Repo	ort Description	Treatment		
Hyperhidrosis	1	Night sweats				
Weight decreased						
Medicine Details: ZOLOFT (Suspected)		Rea	son:			
Tablet	50.0	Milligram	· ·	Oral		
3atch:	Started:	Stopped:				
_aboratory Investigati	ons: Range Date Tes	ted Result		Details		
y y y y	3 3 1 1 1 1					
Additional Information	:					
ort Run 27/07/200 03:29PN	Database: pusime		ADRS004	Page 324 of 591		



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number:	160233	Seq:	1		(Gender: F		
Reported:	22/12/200	_			1	Weight:		
Hospitalisation:						Age:		
Onset Date:						DOB:		
Outcome:	Not yet re	covered			Са	usality : Ca	usality poss	ible
Reaction Detai		<u> </u>						
Preferre	d Term	Seve	erity	Report	Description		Treatment	
Weight increased	i							
Medicine Deta	ails:			Reaso	on:			
Tablet			0.0			Oral		
3atch:		3ta	rted:		Stopped:			
Laboratory In	vostinat	ions:						
Date	Type	Range	Date Tested	Result		Details		
Additional Inf	ormatio	1:						
eport Run 27/07/200	03:29PN	Database: pu	sime	A	DRS004		Page 325	of 591



Age:

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:

Onset Date: DOB:
Outcome: Unknown Causality: Causality possible

Reaction Detai

Hospitalisation:

Preferred Term	Severity	Report Description	Treatment
Alopecia			

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking oral contraceptive.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

rtcaction Betai			
Preferred Term	Severity	Report Description	Treatment
Dyspnoea			
Weight increased			

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

Started: 01/09/1999 Stopped:

Laboratory Investigations:

Date	Туре	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**

Case Numbe Reported Hospitalisation Onset Date	d: 22/12/200 n:	Seq:	1			Gender: F Weight: Age: DOB:		
	e: Unknown				C	Causality: Ca	ausality poss	ible
Reaction Det		i	1			i		
	red Term	Seve	erity	Repor	t Description		Treatment	
Weight increas	ed					Zoloft st	opped	
Medicine De ZOLOFT (Suspe	etails:			Reas	on:			
Tablet	•		50.0 Milli		Daily	Oral		
3atch:		3ta	rted:		Stopped:			
Laboratory	Investigat	tions:						
Date	Туре	Range	Date Tested	Result		Details		
Additional I	nformatio	n:						
Report Run 27/07/	200 03:29PM	Database: pu	sime	A	.DRS004		Page 328	of 591



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Numb	ed: 22/12/2000	Seq: 1				Gender: F Weight:		
Report Hospitalisati						weight: Age:		
Onset Da						DOB:		
	ne: Unknown					Causality: C	ausalitv possi	ible
Reaction De							7 17 17	
	erred Term	Severity	/	Repor	t Description		Treatment	
Dizziness								
_	wal syndrome							
Nausea								
Tremor								
Medicine [Details:							
ZOLOFT (Sus				Reas				
Tablet			50.0 Milli	igram	Daily	Oral .		
3atch:		Started	:		Stopped	d:		
	y Investigat <u>io</u>	ns:						
Date	Туре	Range Da	te Tested	Result		Details		
A al aliti a a l	l							
Additional	Information:							
	7/000	B. ()			DD005			
port Run 27/0	7/200 03:29PN	Database: pusime	91	Α	DRS004		Page 329	ot 591



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

Report Detail	Re	ро	rt C	Deta	il
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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 Detai

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	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Case Number: 160241 Reported: 22/12/20 ospitalisation: Onset Date: 31/05/20 Outcome: Not yet re	00		Gender: F Weight: Age: DOB: Causality: Causality possible
eaction Detai Preferred Term	Severity	Report Description	on Treatment
aggression anxiety Confusional state Drug withdrawal syndrome		. ropon a coorpan	
		₹eason:	
	50.0 M Started:	illigram Daily	Oral opped:
ZOLOFT (Suspected) Tablet		illigram Daily	
Tablet	Started:	illigram Daily	

Additional Information:

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



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

roport zotan			
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 Detai

Report Detail

teaction Detai			
Preferred Term	Severity	Report Description	Treatment
Abnormal dreams			
Diarrhoea			
Hot flush			
Nausea			
Tremor			

Medicine Details:

ZOLOFT (Suspected)		Reason: Depre	ession
Tablet	50.0 Milligram	1 time	Oral
3atch:	Started:	Sto	opped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Although post-menopausal, patient had not previously experienced hot flushes a nd that these have only occurred after taking zoloft.



Onset Date: 28/05/2000 Outcome: Recovered action Detai Preferred Term	Seq: 1			ender: F /eight:
ospitalisation: Onset Date: 28/05/2000 Outcome: Recovered eaction Detai Preferred Term	Severity		V	_
Onset Date: 28/05/2000 Outcome: Recovered eaction Detai Preferred Term	Severity			
Outcome: Recovered eaction Detai Preferred Term	Severity			Age: 30Y
eaction Detai	Severity		_	DOB:
Preferred Term	Severity		Cau	sality: Causality possible
		Penort D	escription	Treatment
ricadacric	i i	Severe headache	CSCIPTION	Zoloft ceased.
Medicine Details: ZOLOFT (Suspected)		Reason:		
Tablet	50.0	Milligram Da	ily O	ral
3atch:	Started: 28			0/05/2000
Laboratory Investigations	s:			
		nta d Dagwit		Details
	Range Date Tes	sted Result		



Case Number: 160247 Reported: 22/12/2000 ospitalisation:	Seq: 1				: : 20Y
Onset Date: 29/05/2000	orod			DOB	: : Causality possible
Outcome: Not yet recoveraction Detai	ereu			ausanty	. Causality possible
Preferred Term	Severity	Repo	ort Description		Treatment
/omiting	1	'	<u>'</u>		
ledicine Details: ZOLOFT (Suspected)		Rea	son:		
Tablet 3atch:	Tablet 50.0 3atch: \$tarted: 28/r		Daily Stopped:	Oral 29/05/200	
ahoratory Invostigation					
aboratory Investigation Date Type	Range Date Tes	ted Result		Deta	ails



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Urticaria		Itchy rash on abdomen, legs, back	

Medicine Details:

ZOLOFT (Suspected) Reason:

 Tablet
 100.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 20/05/2000
 3topped:
 29/05/2000

Laboratory Investigations:

Date	Туре	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).



eport Detai							
ase Number: 1602	250 Seq :	1			Gender: N	Л	
Reported: 22/1	2/2000				Weight:		
spitalisation:					Age: 4	4Y	
Onset Date:					DOB:		
Outcome: Reco	overed				Causality: (Causality poss	ible
ction Detai					_		
Preferred Ter	m Se	verity	Repo	t Description		Treatment	
nnesia					Zoloft	ceased.	
edicine Details: DLOFT (Suspected)			Reas	son:			
Tablet		50.0 Millio		Daily	Oral		
3atch:	31	arted:	J. 5	3topp		5D	
hawatawa laasaa	li mati a ma						
Date Type	Range	Date Tested	Result		Details		
.,,,,,	i iemge						
dditional Inform	ation:						
ort Run 27/07/200 03	3:29PN Database: p	ousime	A	ADRS004		Page 336	of 59



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160253 Reported: 22/12/2000 Hospitalisation: Onset Date: Outcome: Unknown	Seq : 1		We	nder: M eight: Age: 48Y DOB: eality: Causality possible
eaction Detai			Caus	dailty. Causality possible
Preferred Term	Severity	Report C	Description	Treatment
Libido decreased				
Medicine Details: ASIG (Other drug)		Reason :	:	
3atch:	0.0 Started:		Stopped:	
ZOLOFT (Suspected)	7.0.1.001	Reason		
Tablet	100.0 M		aily Ora	al
Batch:	Started:	C	Stopped:	
_aboratory Investigati				
Date Type	Range Date Teste	ed Result		Details
Additional Information	:			
eport Run 27/07/200 03:29PN	Database: pusime	ADF	RS004	Page 337 of 591



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160257 Seq: 1 Gender: F Reported: 22/12/2000 Itospitalisation: Age: 38Y Onset Date: DOB: Outcome: Recovered Causality: Causality poseaction Detai Preferred Term Severity Report Description Treatmen Insomnia Zoloft ceased. therap changed to aropax. Tinnitus Medicine Details: ZOLOFT (Suspected) Reason: Tablet 50.0 Milligram Daily Oral Batch: Started: Stopped:	t
Onset Date: Outcome: Recovered	t
Outcome: Recovered seaction Detail Preferred Term Severity Report Description Treatmen nsomnia Zoloft ceased, theraj changed to aropax. Finnitus Medicine Details: ZOLOFT (Suspected) Reason: Tablet 50.0 Milligram Daily Oral 3atch: Started: Stopped:	t
Preferred Term Severity Report Description Treatmen nsomnia Zoloft ceased. theral changed to aropax. Finnitus Medicine Details: ZOLOFT (Suspected) Reason: Tablet 50.0 Milligram Daily Oral 3atch: Started: Stopped:	t
Preferred Term Severity Report Description Treatment and a Zoloft ceased. therappend to aropax. Value of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the company of the	
Medicine Details: Zoloft ceased, theragchanged to aropax. Medicine Details: ZOLOFT (Suspected) Tablet 50.0 Milligram Dalily Oral 3atch: Started: Stopped:	
Medicine Details: ZOLOFT (Suspected) Tablet 50.0 Milligram Daily Oral 3atch: 3tarted: 3topped:	<u></u>
Medicine Details: ZOLOFT (Suspected) Tablet 50.0 Milligram Daily Oral 3atch: Started: Stopped:	
Tablet 50.0 Milligram Daily Oral 3atch: Started: Stopped:	
Tablet 50.0 Milligram Daily Oral 3atch: 3tarted: 3topped: Laboratory Investigations:	
Tablet 50.0 Milligram Daily Oral 3atch: 3tarted: 3topped:	
Tablet 50.0 Milligram Daily Oral 3atch: Started: Stopped:	
Tablet 50.0 Milligram Daily Oral 3atch: Started: Stopped:	
Tablet 50.0 Milligram Daily Oral 3atch: 3tarted: 3topped:	
Tablet 50.0 Milligram Daily Oral 3atch: 3tarted: 3topped: Laboratory Investigations:	
Tablet 50.0 Milligram Daily Oral 3atch: Started: Stopped: _aboratory Investigations:	
_aboratory Investigations:	
_aboratory Investigations:	
Date Type Range Date Tested Result Details	
Additional Information:	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104011011 20141		-	-
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	Daily	Oral
3atch:	Started:		3	topped:

Laboratory Investigations:

Date	Туре	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**

Case Number: 160260 Reported: 22/12/2000 Hospitalisation:	Seq: 1	Gender: M Weight: Age: 51Y			
Onset Date:				DOB:	
Outcome: Not yet red	overed		Cau	sality: Causality possible	
eaction Detai	1	1		<u> </u>	
Preferred Term	Severity	Repo	rt Description	Treatment	
Arthralgia		Sore hips, knees,	base of skull		
Myalgia					
Medicine Details: ZOLOFT (Suspected)		Reas	son:		
Tablet	10.0) Milligram	Daily O	ral	
3atch:	Started:		Stopped:		
Laboratory Investigati					
Date Type	Range Date Te	ested Result		Details	
Additional Information	:	•			
eport Run 27/07/200 03:29PN	Database: pusime	, ,	ADRS004	Page 340 of 591	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160264 Reported: 22/12/2000 ospitalisation: Onset Date: Outcome: Unknown	Seq: 1	: 1 Gender: F Weight: Age: DOB: Causality: Causality pos				
action Detai						
Preferred Term	Severity	Repor	t Description	Treatment		
air texture abnormal		Hair would not hol	d a perm			
edicine Details: ZOLOFT (Suspected)		Reas	on:			
Tablet	0.0		Ora	al		
3atch:	Started:		Stopped:			
aboratory Investigatio Date Type	ns: Range Date Te:	sted Result		Details		
dditional Information:						
ort Run 27/07/200 03:29PN	Database: pusime	A	DRS004	Page 341 of 591		



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number	: 160265	Seq:	1			Gender: F		
Reported	: 22/12/200	0				Weight:		
Hospitalisation						Age:		
Onset Date	:					DOB:		
	: Unknown				•	Causality: Ca	ausality poss	ible
Reaction Deta		<u> </u>	<u> </u>					
	ed Term	Seve	erity	Repor	t Description		Treatment	
Hyperprolactina	iemia		Elev	ation in prolac	tin levels.			
Medicine De				Reas	on:			
Tablet			0.0			Oral		
3atch:		3ta	rted:		Stopped:			
Laboratory I	nvestigat	ions:						
Date	Type	Range	Date Tested	Result		Details		
Additional Ir	nformatio	n:						
Report Run 27/07/2	00 03:29PN	Database: pu	sime	A	DRS004		Page 342	of 591



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

Report Do	etail
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 Case Number:
 160267
 Seq: 1
 Gender:
 F

 Reported:
 22/12/2000
 Weight:

Hospitalisation:
Onset Date: 01/09/2000
DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Hot flush			

Medicine Details:

DEPO-PROVERA (Suspected)			Reason:		
Oral application	0.0			Oral	
3atch:	Started:			Stopped:	
ZOLOFT (Suspected)			Reason:		
Tablet	25.0	Milligram	Daily	Oral	
Зatch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient on zoloft 25mg increased to 50mg. p/h of hormone imbalance.



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

Report Detail	Re	ро	rt C	Deta	il
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 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 Detai

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	Туре	Range	Date Tested	Result	Details

Additional Information:

Genital herpes - no problems since starting sertraline - almost constant befor e.



eport Detai∣				
ase Number: 160332	Seq: 1		1	Gender: M
Reported: 22/12/2000				Weight: 0.00
spitalisation:				Age: 25Y
Onset Date:				DOB:
Outcome: Unknown			Ca	ausality: Causality possible
ection Detai		<u> </u>		
Preferred Term	Severity		ort Description	Treatment
east mass		Breast lump, bio	opsied but no result	1
adialna Datalla.				
edicine Details: DLOFT (Suspected)		₹e	ason:	
(****)	100.0) Milligram		Oral
Batch:	Started:			
b a wat a w I ba va a ti avati a wati				
		ested Result		Details
		ested Result		Details
		ested Result		Details
aboratory Investigation Date Type		ested Result		Details
		ested Result		Details
		ested Result		Details
Date Type		ested Result		Details
		ested Result		Details
Date Type		ested Result		Details
Date Type		ested Result		Details
Date Type		ested Result		Details
Date Type		ested Result		Details



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

Rep	ort	Detail
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Case Number: 160398 Seq: 1 Gender: F
Reported: 04/01/2001 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Cough	Dry tickling cough, 3-4 bursts of coughing		

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Paily

Stopped:

Laboratory Investigations:

Date	Туре	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.



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

Report	Detai∣
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Anxiety			
Diarrhoea			

Medicine Details:

ZOLOFT (Suspected)			Reason:		
Tablet	50.0	Milligram	Daily		Oral
3atch:	Started:	L	TERM	Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
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)

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 Started:
 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had a history of sensitivity to other medications including maxolon.



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

Re	poi	t D	etai	l
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 Case Number:
 160422
 Seq: 1
 Gender: F

 Reported:
 05/01/2001
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

104011011 20141		-	
Preferred Term	Severity	Report Description	Treatment
Headache	Severe	Severe headaches.	
Hypertension			

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 6.2 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient is an extremely drug sensitive individual.



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

Rep	ort	Detail
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Case Number: 160424 Seq: 1 Gender: M
Reported: 05/01/2001 Weight:
Hospitalisation: Age:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Became psychotic or manic.	

Medicine Details:

ZOLOFT (Suspected)

Tablet 50.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient was refered to a psychiatrist.



Report De	tail								
Hospitalisation	ed: 05/01/200 on:		1		Gender: M Weight: Age: 10Y DOB: Causality: Causality possible				
Reaction De			_						
Pref	erred Term	Seve	erity	Repor	Descriptio	n Treatment			
Urticaria			Hive	like rash.		Zoloft ceased.			
Medicine I				Reas	on.				
Tablet			25.0 Milligram			Oral			
3atch:	:	€ta	rted:		Stopped:				
l ab a vata v	y Investigat	i ons: Range		Result		Details			
		Range				Details			
Date	Туре	. tange	Date Tested	Result					



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

Report D)etail
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Case Number: 160428 Seq: 1 Gender: F
Reported: 05/01/2001 Weight:
Hospitalisation: Age: 75Y

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

todotion botal		-	
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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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**

Case Numb	oer: 160430	Seq:	1		Gender: F					
Report	ted: 05/01/2001	_				Weigh	t:			
lospitalisati	on:					Age	e: 27Y			
	Onset Date:					DOE				
	me: Recovered				Causality	: Causality poss	ible			
eaction D			-							
	ferred Term	Sev	erity/	Repo	rt Descri	ption	Treatment			
Headache										
Vomiting										
Medicine I	Details:									
ZOLOFT (Sus	spected)			Reas	son:					
Table	t		50.0 Mill	igram	Daily	Oral				
3atch	:	3t	arted:			Stopped:				
Laborator	y Investigation	ons:								
Date	Туре	Range	Date Tested	Result		De	tails			
Additional	I Information	:								
port Run 27/0	07/200 03:29PN	Database: p	usime		ADRS004		Page 353	of 501		
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Case Number: 160431

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Reported: 05/01/2001 Hospitalisation: Onset Date:		Weight: Age: 80Y DOB:							
Outcome: Unknown					Causality possible				
eaction Detai	<u> </u>		15 : ::	 					
Preferred Term	Severity	Repo	rt Description	on	Treatment				
Diarrhoea Nausea									
Medicine Details: ZOLOFT (Suspected)		₹ea	son:						
Tablet	50.0	Milligram	Daily	Oral					
Laboratory Investigatio	nne:								
Date Type	Range Date Test	ed Result		Details					
Additional Information	:								
eport Run 27/07/200 03:29PN	Database: pusime		ADRS004		Page 354 of 591				



Report De	tail									
Case Numb	oer: 160432	Seq: 1				Gendei	r: M			
Report	ted: 05/01/200					Weight	t:			
Hospitalisati						_	e: 49Y			
Onset Da						DOB				
Outco	me: Unknown					Causality	: Causality possible			
Reaction D	etai									
Pref	ferred Term	Severi	ity	Repor	Description		Treatment			
Pruritus			Itchy	, irritated scal	ρ.					
Madiaina	Dotoilo									
ZOLOFT (Sus			Reason:							
Table			50.0 Milli		Daily	Oral				
3atch		Starte		9	Stopped:					
I aborator	y Investigat	ions:								
Date	Type		Date Tested	Result		De	tails			
20.0	- 750	1390								
Additiona	l Informatio	n:								



Report De	etail								
Repor Iospitalisat Onset D	ate:	Seq: 1		Gender: M Weight: Age: DOB:					
	me: Unknown				С	ausality:	Causality po	ossible	
eaction D		Carrani	4.	Danad	- Description	<u> </u>	Tranton	- nt	
	eferred Term phageal reflux o	Severi		ses him to vor	Description		Treatm	ent	
Medicine ZOLOFT (Su:				Rease	on:				
Table	et		200.0 Milli	gram	Daily	Oral			
3atch	1:	Starte	d:	L TERM	Stopped:				
	ry Investigat			Don't		Dutil			
Date	Туре	Range D	ate Tested	Result		Detail	S		
Additiona	ıl Informatio	n:							
	07/000 00/0051	Detales			DD0004				



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Severity Itchy	Report Desc eyes.		Causality possible Treatment
	·	DOB: Causality:	
	·	Causality:	
	·		
	·	cription	Treatment
	·	cription	Treatment
Itchy	eyes.		
	Poseon:		
0.0	\6a3UII.	Oral	
		5	
ange Date Lested	Result	Detail	8
	0.0 Started:	Started:	0.0 Oral Started: Stopped:



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number	: 160436	Seq:	1		(Gender: F			
	: 05/01/200	_				Weight:			
Hospitalisation						Age:			
Onset Date	:				DOB:				
Outcome	Unknown				Ca	usality: Causality possible			
Reaction Deta	ni								
Preferr	ed Term	Seve	erity	Repor	Description	Treatment			
Dyspepsia						Treated with zantac. zoloft is continuing.			
Medicine De				Reas					
Tablet	ileu)		0.0	(easi		Oral			
3atch:		Sta	rted:		Stopped:	Sidi			
Laboratory I			Data Tastad	Desult		Dataila			
Date	Туре	Range	Date Tested	Result		Details			
Additional Ir	ıformatio	n:							
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

 3atch:
 3tarted: 15/07/2000
 3topped: 17/07/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking prednisone.



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Numb	ber: 160439	Seq:	1			Gender: F		
Report	ted: 05/01/200	_				Weight:		
lospitalisati	ion:					Age: 2	6Y	
Onset Da	ate:					DOB:		
Outco	me: Recovered	l				Causality: C	ausality poss	ible
eaction D		<u> </u>						
Pref	ferred Term	Seve	erity	Report	Description		Treatment	
Agitation								
Anxiety								
Medicine				Reaso	on:			
Table			50.0 Milli		Daily	Oral		
3atch		3ta	Started: Stoppe					
_aborator Date	y Investigati Type	ONS: Range	Date Tested	Result		Details		1
Date	Туре	range	Date Tested	rvesuit		Details		
Additiona	l Informatior	1 :						
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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number	: 160440	Seq:	1		Gen	der: F
	: 05/01/200	_			We	ight:
Hospitalisation	:					Age:
Onset Date						OOB:
Outcome	: Unknown				Causa	ality: Causality possible
Reaction Deta		<u> </u>	<u>i</u>			,
Prefer	ed Term	Seve	erity	Report	Description	Treatment
Dyspepsia						
Medicine De						
ZOLOFT (Suspe	cted)		0.0	Reaso		
Tablet 3atch:		240	0.0 rted:		Oral	
satch:		วเล	rtea:		Stopped:	
Laboratory						
Date	Туре	Range	Date Tested	Result		Details
Additional li	nformatio	n:				
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: 3tarted: 01/01/1998 3topped:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 11/10/2000 3topped: 06/12/2000

Laboratory Investigations:

Date	Туре	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.



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

Report Detail	Re	ро	rt C	Deta	il
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 Case Number:
 160470
 Seq: 1
 Gender: M

 Reported:
 09/01/2001
 Weight:

Hospitalisation: Age: 73Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todotion Dotal		_	
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
3atch:	Started:		Sto	opped:

Laboratory Investigations:

Date	Туре	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.



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

Report Detail	Re	ро	rt C	Deta	il
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 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

104041011 20441		-	
Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

ZOLOFT (Suspected) Reason:
Tablet 50.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient on zoloft for 3 weeks showed elevated Ift's.



Report Detail								
Case Number: 1 Reported: 0 ospitalisation:		Seq:	1				Gende Weigl Ag	
Onset Date: 1	4/11/1999)					DO	
Outcome: N	lot yet rec	overed				C	ausalit	y: Causality possible
eaction Detai							-	
Preferred	Term	Seve	erity	Repor	Descri	iption		Treatment
Confusional state								
Medicine Detai		eted)		Reas	on:			
Injection			0.0				Intraver	nous
3atch:		3tar	ted:			Stopped:		
ZOLOFT (Suspected)			Reas				
Tablet			50.0 Milli	gram	Daily		Oral	
3atch:		3tar	ted:			Stopped:		
.aboratory Inv Date T	estigati (ONS: Range	Date Tested	Result			D	etails
Additional Info								



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160474 Reported: 09/01/2001 ospitalisation: Onset Date: 01/12/1999 Outcome: Not yet reco	Seq: 1		DO	ht: ge: 36Y
action Detai Preferred Term	Severity	Report Des	scription	Treatment
aculation failure	Coverity	r toport Bot	Jon Palen	ricaliioni
bido decreased				
ledicine Details: ZOLOFT (Suspected)		₹eason:		
Tablet 3atch:	50.0 Mil Started:	ligram Daily	/ Oral Stopped:	
aboratory Investigatio				
Date Type	Range Date Tested	Result	D	etails
dditional Information:		<u> </u>		
ort Run 27/07/200 03:29PN	Database: pusime	ADRSO	004	Page 366 of 591



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

 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 Detai

Preferred Term	Severity	Report Description	Treatment
Chills			
Diarrhoea			
Vomiting			Given klacid and panamax.

Medicine Details:

ZOLOFT (Suspected) Reason:

 Tablet
 50.0
 Milligram
 Daily
 Oral

 3atch:
 3tarted:
 14/01/2000
 3topped:
 20/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking nordiol, flixotide, propionate, ventolin.



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

Report Detail	Re	ро	rt C	Deta	il
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 Case Number:
 160476
 Seq: 1
 Gender:
 F

 Reported:
 09/01/2001
 Weight:

Hospitalisation: Age: 22Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

<u> </u>			
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

 3atch:
 3tarted:
 14/01/2000
 3topped:
 20/01/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

See seq 01 for other drugs.



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160489 Reported: 09/01/2001 ospitalisation: Onset Date: Outcome: Unknown	Seq: 1		Gender: M Weight: Age: 45Y DOB: Causality: Causality possible			
eaction Detai						
Preferred Term	Severity	Repor	t Description	Treatment		
opecia						
edicine Details:		Reas	on:			
Tablet	50.0 M)ral		
3atch:	Started:	iiiigi airi	Stopped:			
aboratory Investigatio	ns:					
Date Type	Range Date Tester	d Result		Details		
dditional Information:	•	•				
ort Run 27/07/200 03:29PN	Database: pusime	A	NDRS004	Page 369 of 591		



Case Number: 160490 Reported: 09/01/2001			
ospitalisation: Onset Date:	Seq: 1	Weig A De	Age: OB:
Outcome: Unknown		Causa	lity: Causality possible
eaction Detai Preferred Term	Coverity	Danart Description	Trootmont
Dizziness	Severity	Report Description though she were about to "pass	Treatment
Medicine Details: BREVINOR-1 (Other drug) Tablet	0.0	Reason:	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet 3atch:	50.0 Milligram Started:	Daily Oral Stopped:	
_aboratory Investigatio		esult	Details



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

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 Detai

Preferred Term	Severity	Report Description	Treatment
Somnolence			

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 50.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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**

Case Number: 160495 Reported: 09/01/2001 Hospitalisation: Onset Date: Outcome: Recovered	Seq: 1		DOB	: : 70Y
eaction Detai Preferred Term	Severity	Report Des	crintion	Treatment
Agitation	Seventy	report Des	Cription	rreatment
Medicine Details:		2		
ZOLOFT (Suspected) Tablet	50.0 Mil	Reason: Iigram Daily	Oral	
3atch:	Started:	iigrafii Daiiy	Stopped:	
_aboratory Investigatio	one:			
Date Type	Range Date Tested	Result	Det	ails
Additional Information				
eport Run 27/07/200 03:29PN	Database: pusime	ADRS0	04	Page 372 of 591



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

 3atch:
 3tarted: 01/09/1999
 \$topped: 28/11/1999

Laboratory Investigations:

Date	Туре	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.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Num	ber: 160497	Seq: 1		Gender: F					
	ted: 09/01/2001	-	Weight:				:		
ospitalisat	ion:						.ge: 70Y		
Onset D	ate:					DOB	:		
Outcome: Recovered						Causality	: Causality poss	ible	
action D									
Pre	ferred Term	Severi	ty	Repo	rt Descri	ption	Treatment		
izziness									
ausea									
ledicine	Dotaile								
ZOLOFT (Su	spected)			₹ea	son:				
Table			50.0 Milli		Daily	Oral			
3atch		Starte			,	Stopped:			
	y Investigation								
Date	Туре	Range D	ate Tested	Result		Deta	ails		
dditiona	I Information:								
uuitiona	i iiiioiiiiatioii.								
ort Run 27/0	07/200 03:29PN [Database: pusin	ne		ADRS004		Page 374	of 591	



eport Detail								
ase Number:		Seq:	1			Gender: 1	M	
Reported: 09/01/2001					Weight:			
spitalisation:						Age:	55Y	
Onset Date:		_				DOB:		
Outcome: Not yet recovered						Causality: (Causality possible	е
ction Detai Preferred	Term	Seve	erity.	Ren	ort Description		Treatment	
ectile dysfunction		OCV		ection difficult			Treatment	
edicine Deta			400		ason:			
Tablet 3atch:		.	100.0 M rted:	lilligram	Daily	Oral ped:		
boratory Inv	vestigation	e.						
		Range	Date Tested	d Result		Details	·	
lditional Info	ormation:							
rt Run 27/07/200	03:29PN D	atabase: pu	sime		ADRS004		Page 375 of	f 59 ⁻



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160499 Reported: 09/01/2007 Hospitalisation: Onset Date: Outcome: Recovered			Gender: M Weight: Age: DOB: Causality: Causality possible			
eaction Detai						
Preferred Term	Severity	Repor	t Description	Treatment		
nsomnia				Dose was reduced to 50mg.		
Medicine Details: ZOLOFT (Suspected)		Reas	on:			
Tablet	100.0 Mi	lligram	Daily Or	al		
_aboratory Investigati	Ons: Range Date Tested	Result	T	Details		
Турс	Trainge Bate residu	recount		Details		
Additional Information	1:					
port Run 27/07/200 03:29PN	Database: pusime	Α	DRS004	Page 376 of 591		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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	Туре	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.



0		O
Seq: 1		Gender: F
		Weight:
		Age: 25Y DOB:
word		
overed		ausality: Causality possible
Severity	Report Description	Treatment
	Reason:	Out
		Oral
ons:		
P ns: Range Date Tested	Result	Details
	Seq: 1 Severity Nau 0.0 Started:	Severity Report Description Nausea for the first 2 weeks. Reason: 0.0



Report Detail					
Case Number: 160597	Seq: 1			Gender: F	
Reported: 15/01/200				Weight:	
ospitalisation:				Age : 58Y	
Onset Date:				DOB:	
Outcome: Recovered	d			Causality: Causa	llity possible
eaction Detai					3 1
Preferred Term	Severity	Repo	ort Description	Tr	reatment
achycardia				Zoloft cease cipramil.	d and switched to
ledicine Details: ZOLOFT (Suspected)		Res	ason:		
Tablet	50.0	Milligram	Daily	Oral	
3atch:	Started:		Stoppe	ed:	
aboratory Investigat Date Type	Range Date Te	ested Result		Details	_
Dute Type	range Bate re	Tesan		Betallo	
Additional Information	n:				
ort Run 27/07/200 03:29PN	Database: pusime		ADRS004		age 379 of 591



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
Onset Date:
DOB:

Outcome: Recovered Causality: Causality certain

Reaction Detai

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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



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

Re	po	rt	D	etail
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Case Number: 160600 Seq: 1 Gender: M
Reported: 15/01/2001 Weight:
Hospitalisation: Age: 35Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Ejaculation failure			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

3atch:

\$topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient switched onto an alternate ssri.



-	15/01/2001					Weigh	
spitalisation:						_	e : 23Y
Onset Date:						DOI	
Outcome:	Recovered					Causalit	y: Causality possible
action Detai		1 _	-			1	
Preferred	I Term	Seve			ort Description		Treatment
usea			Pa	atient develope	ed constant nause	a.	
edicine Deta				302	ason:		
Tablet	u,		50.0	Milligram	Daily	Oral	
3atch:		3ta	rted:	viiiigi airi	Stoppe		
horatory Inv	vestigations	g.					
		S: Range	Date Teste	ed Result			etails
			Date Teste	ed Result			etails
			Date Teste	ed Result			etails
			Date Teste	ed Result			etails
			Date Teste	ed Result			etails
			Date Teste	ed Result			etails
Date	Туре		Date Teste	ed Result			etails
boratory Inv	Туре		Date Teste	ed Result			etails
Date	Туре		Date Teste	ed Result			etails



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160603	Seq: 1			Gender: F
Reported: 15/01/200	1			Weight:
spitalisation:				Age: 33Y
Onset Date:				DOB:
Outcome: Not yet re	covered		C	ausality: Causality possible
action Detai				1
Preferred Term	Severity	•	t Description	Treatment
norgasmia		Continual anorga	smia.	Increased the dose to 200mg, her depression is lifting but the anorgasmia is still a problem.
edicine Details:	DE (Suspected)	₹eas	son:	
Tablet	100.0	Milligram	Daily	Oral
3atch:	Started:		3topped:	
aboratory Investigat	ions: Range Date Tes	sted Result		Details
dditional Information	n:			
ort Run 27/07/200 03:29PN	Database: pusime	,	ADRS004	Page 383 of 591



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160605 Reported: 15/01/200 lospitalisation: Onset Date: Outcome: Not yet rec			Gender: Weight: Age: DOB: Causality:	45Y
eaction Detai Preferred Term	Severity	Report Desc	rintion	Treatment
Hyperprolactinaemia	Seventy	Report Desc	приоп	rreatment
Medicine Details:				
ZOLOFT (Suspected) Tablet	EO O Mil	Reason:	Oral	
Satch:	50.0 Mill Started:	ligram Daily	Oral Stopped:	
aboratory Investigat	Range Date Tested	Result	Deta	ils
Additional Information	ղ։			
oort Run 27/07/200 03:29PN	Database: pusime	ADRS004	4	Page 384 of 591



Report De	etail							
	ber: 160606 ted: 15/01/200	Seq:	1			Gen Wei	der: ght:	F
lospitalisat							Age:	70Y
Onset D		لم					OB:	Coverlity passible
eaction D	me: Recovere	a				Causa	iity:	Causality possible
	eferred Term	Sev	erity	Repor	t Description	on .		Treatment
Nausea		Severe	Seve	ere nausea.				
Medicine ZOLOFT (Su				Reas	on:			
Table			25.0 Mill	ligram	Daily	Oral		
3atcl	h:	Sta	arted:		3to	opped:		
	ry Investigat		Date Tested	Result			Detail	S
Laborato Date	ry Investigat Type	i ons: Range	Date Tested	Result			Detail	S



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: 3tarted: 16/09/1997 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking becloforte, serevent, valium and serepax.



Case Number: 160641 Reported: 15/01/2001 ospitalisation: Onset Date: Outcome: Recovered	Seq: 1						
Onset Date: Outcome: Recovered					Gende Weigh Age		
					DOE		
					Causality	y: Causality proba	able
eaction Detai	Coverity	Ī	Danas	t Decembration		Treatment	
Preferred Term	Severity	TI	Repor atened her hu	t Description		realment	
Aggression Psychotic disorder		Inrea	atened ner ni	isband with a	a kniře.		
ledicine Details: ZOLOFT (Suspected)			Reas	ou.			
Tablet	2	5.0 Milli		Daily	Oral		
3atch:	Started:		g. 		pped:		
aboratory Investigations				1			
Date Type R	lange Date	Tested	Result		De	etails	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 22/07/2000
DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

todolion Botai			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Developed profound hyponatraemia.	
Depersonalisation		Feeling of being "spaced out".	
Agitation			
Anxiety			Patient was given serepax, then admitted to hospital.
Pneumonia			

Medicine Details:

ZOLOFT (Suspected)		Reason:				
Tablet	50.0	Milligram	Daily	Oral		
3atch:	Started:		3to	pped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking serepax and septrin.



Μ

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:

Reported: 15/01/2001 Weight:
Hospitalisation: Age: 34Y
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	0.0		Oral
3atch:	Started:	Stopped:	
PANADEINE FORTE (Suspected)		Reason:	
Tablet	0.0		Oral
3atch:	Started:	Stopped:	
TEMAZEPAM (Suspected)		Reason:	
Capsule	0.0		Oral
3atch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient taking zoloft overdosed on a combination of drugs (unsure of quantity)



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Dotal		_	
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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Later patient had vaginal bleeding, lasting for 3 weeks resulting in a curette in august.



Case Number: 160654 Reported: 15/01/2001 Spitalisation: Onset Date: Outcome: Recovered action Detai				DOB	: : 25Y
Preferred Term	Severity	Report	Description	n	Treatment
onvulsion	Pat	ient experienced	a fit.		
ledicine Details:					
EPILIM (Interaction)		Reason	n:		
Tablet	0.0		Oral		
3atch:	Started:		Stopped:		
ZOLOFT (Interaction)	E0.0 A41	Reason		Oral	
Tablet 3atch:	50.0 Mi Started:	ınıgram l	Daily	Oral pped:	
aboratory Investigati	ons:				
Date Type	Range Date Tested	Result		Det	ails



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Reported: 15/0 pspitalisation: Onset Date: Outcome: Recordant Preferred Tenton Detail Onvulsion Redicine Details: COLOFT (Suspected)	m S	everity	Report		Peight: Age: 88Y DOB: sality: Causality possible Treatment
Onset Date: Outcome: Reco action Detai Preferred Ter onvulsion edicine Details:	m S	everity	Report	Caus	DOB: sality: Causality possible
Outcome: Reco	m S	everity	Report	Caus	sality: Causality possible
Preferred Ter onvulsion	m S	everity	Repor		
Preferred Teronvulsion edicine Details:		everity	Report	t Description	Treatment
edicine Details:		everity	Repor	t Description	Treatment
edicine Details:					
OLOFT (Suspected)					
			Reas	on:	
Tablet		50.0 Milli	igram	Daily Ora	al
3atch:		Started:		Stopped:	
boratory Invest	tigations:				
Date Type	Range	Date Tested	Result		Details



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160674	Seq: 1		Gender:	F
Reported: 17/01/2001			Weight:	001
espitalisation:			Age:	θUΥ
Onset Date:			DOB:	Oarradit rassaible
Outcome: Recovered			Causanty:	Causality possible
action Detai Preferred Term	Severity	Report Descr	intion	Treatment
nxiety	Ocverity	report Descr	ption	rreatment
ledicine Details: CAFFEINE (Suspected)	0.0	Reason:		
3atch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	• • • • • • • • • • • • • • • • • • • •	
Tablet	100.0 M		Oral	
3atch:	Started:	3 '	Stopped:	
aboratory Investigation				
Date Type	Range Date Tested	d Result	Details	3
Additional Information:	•	, 1		
oort Run 27/07/200 03:30PN	Database: pusime	ADRS004		Page 393 of 591



eport Detai∣						
ase Number: 16067	'8 Seq : 1			Ge	nder: F	
Reported: 17/01				We	eight:	
spitalisation:					Age: 70Y	
Onset Date:					DOB:	
Outcome: Unkno	own			Caus	ality: Causality poss	ible
action Detai					,	
Preferred Tern	n Sever	ity	Report	Description	Treatment	
atulence		Abdor	minal distentio	n		
edicine Details: DLOFT (Suspected)			Reaso	1:		
Tablet		0.0		Ora	I	
3atch:	Starte	ed:		Stopped:		
aboratory Investi	gations:					
Date Type		Date Tested	Result		Details	
dditional Informa	tion:					
rt Run 27/07/200 03:	30PN Database: pusir	mei	ΑΠ	RS004	Page 394	of 501



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160679	Seq: 1			Gender: F
Reported: 17/01/2	-			Weight:
ospitalisation:				Age: 30Y
Onset Date:				DOB:
Outcome: Recove	ered		C	ausality: Causality possible
action Detai				
Preferred Term	Severity	Repo	ort Description	Treatment
eadache	Severe	Severe headach	е	
gitation				Zoloft ceased.
ausea				
omiting				
edicine Details:		202	son:	
Tablet	50	.0 Milligram	Daily	Oral
Batch:	Started:	.o willigram	Stopped:	Olai
aboratory Investig Date Type		Tested Result		Details
Date Type	Range Date	rested Result		Details
Additional Informati	ion:			
ort Run 27/07/200 03:30	PN Database: pusime		ADRS004	Page 395 of 591



Report Detai						
Case Number: 16	0680	Seq: 1			Gender:	F
Reported: 17		•			Weight:	
lospitalisation:					Age:	35Y
Onset Date: 05	/06/2000				DOB:	
Outcome: Re	covered			C	ausality:	Causality probable
eaction Detai	_					
Preferred T	erm	Severity	Repor	t Description		Treatment
Rash maculo-papula	ar		Pimple like rash		Zolot	ft ceased.
Medicine Details ZOLOFT (Suspected)	S :		Reas	on:		
Tablet		50.0	Milligram	Daily	Oral	
3atch:		Started: 29	/05/2000	Stopped:	05/06/2000)
Laboratory Inve						
Date Typ	oe Rang	je Date Tes	sted Result		Detai	ls



Report Detail						
Case Number: 16068 Reported: 09/01/2 Iospitalisation: Onset Date: Outcome: Not ye	2000	Gender: F Weight: Age: 35Y DOB: Causality: Causality possible				
eaction Detai Preferred Term	Severity	Ren	ort Descript	ion	Treatment	
Drug level increased	Coverity	Elevated serum			Trodunone	
Medicine Details: CLOZARIL (Interaction)		Re	ason:			
Tablet	0.	0		Oral		
3atch:	Started:			Stopped:		
ZOLOFT (Interaction)	450		ason:	01		
Tablet 3atch:	150. Started:	0 Milligram	Daily	Oral topped:		
Laboratory Investiç						
Date Type	Range Date T	ested Result			Details	
, , , , , , , , , , , , , , , , ,	l J					



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160742 Reported: 17/01/2001 ospitalisation: Onset Date: Outcome: Recovered	Seq: 1		DOB	: 0.00 : 35Y
action Detai Preferred Term	Severity	Repo	ort Description	Treatment
nyroid function test abnormal nyroid disorder	1		ion/increase in thyroid	T GGATTOTAL
Medicine Details: ZOLOFT (Suspected) 3atch:	50.0 Started:	Rea Milligram	son: Daily Oral }topped:	
aboratory Investigations			_	
	ange Date Tes	sted Result	Dei	ails
Date Type Ra				
Date Type Rank				



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Numbe	r: 160743	Seq:	1			Gender: \	J	
Reporte	d: 17/01/20	01		Weight:				
ospitalisatio	ո։					Age: 7	' 0Y	
Onset Date	e:					DOB:		
Outcom	e: Recovere	ed				Causality: (Causality poss	ible
action Det	ai							
Prefe	red Term	Sev	erity	Report	Description		Treatment	
yponatraemia	a							
edicine D	etails:							
OLOFT (Suspe	ected)			Reaso	on:			
Tablet			0.0		Daily	Oral		
3atch:		Sta	arted:		Stopped	l:		
boratory			1					
Date	Туре	Range	Date Tested	Result		Details		
ditional I	nformatic	n.						
aditional i	ntormatic	on:						
rt Run 27/07/	200 03:30P	N Database: pu	usime	А	DRS004		Page 399	of 591
								J. J. 1



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160744 Reported: 17/01/2001 lospitalisation: Onset Date: Outcome: Unknown	Seq: 1		Gender: F Weight: Age: 42Y DOB: Causality: Causality possible
eaction Detai Preferred Term	Severity	Report Description	Treatment
Glaucoma	- coroniy	. topon = coonputer	
ledicine Details: ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milli		Oral
3atch:	Started:	stopp	
aboratory Investigation	ns:		
Date Type	Range Date Tested	Result	Details
additional Information:			
ort Run 27/07/200 03:30PN	Database: pusime	ADRS004	Page 400 of 591



eport Detail Case Number: 160745 Reported: 17/01/2001 espitalisation: Onset Date:	Seq: 1		DO	nt: e: 30Y B:
Outcome: Unknown			Causalit	y: Causality possible
eaction Detai Preferred Term	Severity	Penort	Description	Treatment
Peptic ulcer haemorrhage		reasing bleeding		Heatment
Medicine Details: ZOLOFT (Suspected)		Reason	1:	
Tablet	100.0 M	illigram [Daily Oral	
3atch:	Started:		Stopped:	
	1S: Range Date Tested	d Result	D	etails
_aboratory Investigation		d Result	De	etails



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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	
3atch:	Started:			Stopped:
CLOZAPINE (Suspected)			Reason:	
CLOZAPINE (Suspected)	300.0	Milligram	Reason: Daily	

Laboratory Investigations:

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

Additional Information:

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

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

Medicine Details:

SERTRALINE HYDROCHLORIDE	(Suspected)		Reason:	Depression
	50.0	Milligram	Daily	
3atch:	Started:			Stopped:
CLOZAPINE (Suspected)			Reason:	
CLOZAPINE (Suspected)	300.0	Milligram	Reason: Daily	

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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Dotal			<u> - </u>
Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular		Pimply looking rash lower back, shoulders,	Phenergan 25mg tds and prednisolone 50mg/day. date of recovery: 17/1/2001.
Pruritus			
Pyrexia			

Medicine Details:

TEGRETOL (Suspected)		Reason:	
	400.0 Milligram	Daily	
Зatch:	Started: 01/11/2000	Stopped:	09/01/2001
ZOLOFT (Suspected)		Reason:	
	200.0 Milligram	Daily	
Зatch:	Started:	Stopped:	09/01/2001
LARGACTIL (Suspected)		Reason:	
	25.0 Milligram	Daily	
Зatch:	Started:	Stopped:	09/01/2001
ORUVAIL SR (Suspected)		Reason:	
	200.0 Milligram	Daily	
3atch:	Started:	Stopped:	09/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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

Report Run 27/07/200 03:30PN Database: pusime ADRS004 Page 404 of 591



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

Report Detail				
Case Number: Reported: Hospitalisation: Onset Date:	160854 22/01/2001 09/01/2001 Recovered	Seq: 1	Gender: Weight: Age: DOB: Causality:	72.00 32Y
Medicine Deta ZOTON (Suspecte		30.0 Milligram Started :	Reason: Daily Stopped:	
Laboratory In	vestigations:			
Additional Inf		ly accurate but indicates that	t start occurred sometime during the	e month.

Report Run 27/07/200 03:30PN Database: pusime ADRS004 Page 405 of 591



Case Number: 160866

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Reported: 23/01/2001 lospitalisation:			Weight: Age: 61Y				
Onset Date: 08/08/2000			DOB:				
Outcome: Recovered			Causality:				
eaction Detai		_		•			
Preferred Term	Severity	Repo	rt Description		Treatment		
Dyspnoea		Exertional dyspn	oea				
Agitation							
Cardiac failure							
Hyperventilation							
Medicine Details:		200					
ZOLOFT (Suspected)	0.7		son:	Oral			
Tablet 3atch:	0.0 3tarted:	J	Stopped	Oral			
BETALOC (Suspected)	otarteu.	Çea	son:	-			
Tablet	0.0		- •	Oral			
3atch:	Started:	-	€topped				
NORVASC (Suspected)		Rea	son:				
Tablet	40.0) Milligram	Daily	Oral			
3atch:	Started:		Stopped	:			
Laboratory Investigation Date Type		ested Result	хоррец	Deta	iils		
			<u>I</u>				
Additional Information	:						
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eport Run 27/07/200 03:30PN	Database: pusime		ADRS004		Page 406 of 59		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Depression			Patient recovered 24 hrs later.

Medicine Details:

TELFAST (Interaction)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
ZOLOFT (Interaction)		Reason: Depression	
	25.0 Milligram	Daily	
3atch:	Started: 28/11/2000	Stopped:	
PREMARIN (Other drug)		Reason: Menopausal symptoms	
	625.0 Microgram	Daily	
3atch:	Started: 12/04/2000	Stopped:	
OROXINE (Other drug)		Reason:	
	50.0 Microgram	Daily	
3atch:	Started: 12/04/2000	Stopped:	

Laboratory Investigations:

Date	Туре	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.



Case Number: 160890

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Preferred Term Severity Report Description Treatment Confusional state Fatigue Hyponatraemia Medicine Details: ZOLOFT (Suspected) Tablet 100.0 Milligram Daily Oral Started: Stopped:	Reported:		Weight:						
Outcome: Recovered Searction Details: Preferred Term Severity Report Description Treatment Confusional state Fatigue Hyponatraemia Patient hospitalised. Medicine Details: ZOLOFT (Suspected) Reason: Tablet 100.0 Milligram Daily Oral 3 atch: Started: Stopped:	-	Admitted to	o hospital						
Preferred Term Severity Report Description Treatment Confusional state Fatigue Hyponatraemia Medicine Details: ZOLOFT (Suspected) Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped:									
Preferred Term Severity Report Description Treatment Confusional state Fatigue Hyponatraemia Medicine Details: ZOLOFT (Suspected) Tablet 100.0 Milligram Daily Oral Started: Stopped:		Recovered	l		Causality: Causality probable				
Medicine Details: ZOLOFT (Suspected) Tablet 3atch: 3tarted: 3topped: Acason: Tablet 100.0 Milligram 2topped: Acason: 3topped: Acason: 3topped: Acason: 3topped: Acason: 3topped:		l Tang				4 D	intina	Taratarant	
Addicine Details: ZOLOFT (Suspected) Tablet 100.0 Milligram Daily Oral 3 atch: Started: Stopped:			Sev	rerity	Кероі	τ Descr	iption	reatment	
Medicine Details: ZOLOFT (Suspected) Tablet 100.0 Milligram Patient hospitalised. Oral 3atch: 3tarted: 3topped:									
Medicine Details: ZOLOFT (Suspected) Tablet 100.0 Milligram Paily Oral 3atch: Stopped:	-							Detient beenitelieed	
ZOLOFT (Suspected) Tablet 100.0 Milligram Daily Oral Satch: Started: Stopped: Aboratory Investigations:									
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped:									
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped:									
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped:									
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped: _aboratory Investigations:									
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped:									
Tablet 100.0 Milligram Daily Oral 3atch: Started: Stopped:					3000	· on:			
_aboratory Investigations:		a)		400 0 Millio			0-	al.	
_aboratory Investigations:			24.		gram	Dally		aı	
	Jaton.		3 16	arteu.			stoppeu.		
Date Type Range Date Tested Result Details	_aboratory Inv	vestigati	ons:						
	Date	Туре	Range	Date Tested	Result			Details	
	Additional Info	ormation	n:						
Additional Information:									
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Additional Information:	port Run 27/07/200	03:30PN	Database: po	usime	A	ADRS004		Page 408 of 59	
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

 3atch:
 3tarted:
 01/05/2000
 3topped:
 28/11/2000

Laboratory Investigations:

Date	Туре	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.

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THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160893 Reported: 24/01/2001 Iospitalisation: Onset Date: Outcome: Unknown	Seq: 1		Gender: M Weight: Age: 80Y DOB: Causality: Causality possible
eaction Detai Preferred Term	Severity	Report Description	Treatment
Convulsion	- CONSTRUCTION OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE CONTROL OF THE	. topon 2 cocilp iici.	
M. N. C. Barrella			
Medicine Details: ZOLOFT (Suspected)		Reason:	
Tablet	50.0 Milli		Oral
3atch:	Started:	stopp	
_aboratory Investigatio	ns:		
Date Type	Range Date Tested	Result	Details
Additional Information:			
port Run 27/07/200 03:30PN	Database: pusime	ADRS004	Page 410 of 591



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Cholangitis			
Pancreatitis			

Medicine Details:

ZOLOFT (Suspected)			Reason:	
Tablet	50.0	Milligram	Daily	Oral
3atch:	Started:		3to	pped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

A patient taking zoloft was diagnosed with lymphoplasmocytic sclerosing, pancreatitis and cholangitis.



Report Det	ail							
Case Number: 160896 Seq: 1 Reported: 24/01/2001 Hospitalisation: Admitted to hospital Onset Date: Outcome: Unknown					Gender: M Weight: Age: 35Y DOB: Causality: Causality possible			
eaction De								
Prefe Mania	erred Term	Seve	erity	Repor	Description		Treatment Patient hospitalised.	
Medicine D ZOLOFT (Susp			FO O Million	Reas		Oral		
Tablet 3atch:		Star	50.0 Milli ted:	gram	Daily	Oral pped:		
Laboratory	[,] Investigat	ions:						
Laboratory Date	' Investigat Type	ions:	Date Tested	Result			Details	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 160907 Reported: 23/01/2007 Iospitalisation: Onset Date:	Seq: 1		W	nder: F eight: Age: 79Y DOB:
Outcome: Recovered	I			sality: Causality possible
eaction Detai Preferred Term	Severity	Repo	ort Description	Treatment
Nausea	Severe	Severe nausea	•	
Anorexia				
Andinina Dataila.				
ledicine Details: ZOLOFT (Suspected)		Rea	son:	
Tablet	50.	0 Milligram	Daily Ora	al
3atch:	Started:	· ·	Stopped:	
.aboratory Investigati		octod Dopult		Details
Date Type	Range Date T	ested Result		Details
Additional Information	1:			
ort Run 27/07/200 03:30PN	Database: pusime		ADRS004	Page 413 of 591



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

Report De	etail
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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 Detai

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Galactorrhoea			
Hyperprolactinaemia			

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started:

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking contraceptive pill (unspecified).



Report Detail							
Case Number:	160913	Seq:	1			Gen	der: F
Reported:	24/01/2001	_				Wei	ght:
Hospitalisation:						A	Age: 15Y
Onset Date:						D	OB:
Outcome:	Recovered					Causa	lity: Causality possible
Reaction Detai		<u> </u>					
Preferred		Seve	erity	Repor	t Description		Treatment
Depersonalisation	1						Dose of zoloft decreased to
Medicine Deta			450.0 MW	Reas		0.11	
Tablet			150.0 Milli	gram	Daily	Oral .	
3atch:		Sta	rted:		Stoppe	a:	
Laboratory Inv							
Date	Туре	Range	Date Tested	Result			Details
Additional Info	ormation	:					





eport Detail						
Case Number: 160915	Seq: 1			Gender: F		
Reported: 24/01/2001				Weight:		
spitalisation: Onset Date:				Age: DOB:		
Outcome: Unknown				Causality: C	ausality noss	ihle
action Detai				OddSanty. O	addanty poss	ibic
Preferred Term	Severity	Repor	t Description		Treatment	
uscle spasms		iscle spasms	•			
edicine Details:						
OLOFT (Suspected)		₹eas				
Tablet	150.0 M	iilligram	Daily	Oral		
3atch:	Started:		Stopped	:		
aboratory Investigation		d Decul	Ī	Deteile		
Date Type	Range Date Tester	d Result		Details		
dditional Information:						
ort Run 27/07/200 03:30PN [Database: pusime		ADRS004		Page 417	of 591



Case Number: 160931

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Reported: 25/01/2001	Weight:				
spitalisation:	Age : 69Y				
Onset Date: 27/04/2000				DOB:	
Outcome: Unknown			C	ausality: C	ausality possible
action Detai					
Preferred Term	Severity	Report Des	scription		Treatment
onfusional state					
Convulsion					
lyperreflexia					
lypertonia					
yrexia					
erotonin syndrome					
ledicine Details:					
NEULACTIL (Other drug)		Reason:			
Tablet	0.0			Oral	
3atch:	Started:		Stopped:		
FLORINEF (Other drug)		Reason:			
Tablet	0.0			Oral	
3atch:	Started:		Stopped:		
ZOLOFT (Suspected)		Reason:	Depression		
Tablet	200.0 Milli	gram Dail	/	Oral	
3atch:	Started: 27/04/20		Stopped:	01/05/2000	
aboratory Investigation Date Type	Range Date Tested	Result		Details	
Additional Information:	Range Date Tested	Result		Details	



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

Rep	ort	Detail
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 Case Number:
 160932
 Seq: 1
 Gender: M

 Reported:
 25/01/2001
 Weight:

Hospitalisation: Age: 50Y
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			

Medicine Details:

ZOLOFT (Suspected)

Tablet

100.0 Milligram
Daily
Oral

3atch:
\$topped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

		-	
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:				
	1.0 Dose Unspecified Daily				
3atch:	Started: 01/01/2000 Stopped:				
ZOLOFT (Suspected)	Reason: Depression				

 Tablet
 150.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 27/12/2000
 3topped: 02/01/2001

Laboratory Investigations:

Date	Туре	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.

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

Rep	ort	Detail
-----	-----	--------

 Case Number:
 161004
 Seq: 1
 Gender: F

 Reported:
 25/01/2001
 Weight:

Hospitalisation: Age:
Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Dyspepsia			Ceased zoloft

Medicine Details:

ZOLOFT (Suspected) Reason:

Tablet 200.0 Milligram Daily Oral

3atch: 3tarted: 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient experienced symptoms after increase of zoloft to 200mg daily.



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 161007 Reported: 25/01/200 Hospitalisation: Onset Date: Outcome: Recovered		Gender: M Weight: Age: 20Y DOB: Causality: Causality possible			
Reaction Detai		_			
Preferred Term	Severity	Rep	oort Description	Treatment	
Agitation					
Medicine Details: ZOLOFT (Suspected)		₹,	eason:		
Tablet	5	0.0 Milligram	Daily	Oral	
3atch: Started: Stopped:					
Laboratory Investigati	ions:				
Date Type		Tested Result		Details	
Additional Information	1:				
eport Run 27/07/200 03:30PN	Database: pusime		ADRS004	Page 422 of 591	



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number:	161024	Seq:	1			Gender: F		
Reported:	24/01/2001					Weight:		
spitalisation:						Age:		
Onset Date:						DOB:		
Outcome:					C	Sausality: Ca	ausality poss	ible
action Deta		1 2	., 1			1	<u> </u>	
Preferre		Seve			Description		Treatment	
eonatal disorde	er		Bab	y born with cer	ebral palsy.			
edicine Det			0.0	Reaso	on:	Orol		
Tablet Batch: Star			0.0 Started: Stopp			Oral		
boratory In	Type	Range	Date Tested	Result		Details		
54.0	1,700	rango	Date Toolea	rtoount		Dotallo		
dditional In	formation	:						
ort Run 27/07/20	03:30PN	Database: pus	Sima .	Δ	DRS004		Page 423	of 501



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

lospitalisation: Onset Date: Outcome: Unknown eaction Detai Preferred Term	Severity	Report	I	Age: 88Y DOB: ality: Causality possible Treatment Dose had been reduced from 100mg to 50mg daily.
Outcome: Unknown action Detai Preferred Term	Severity	Report	Caus	Treatment Dose had been reduced from
action Detai Preferred Term	Severity	Report		Treatment Dose had been reduced from
Preferred Term	Severity	Report	Description	Dose had been reduced from
mnesia				Dose had been reduced from 100mg to 50mg daily.
edicine Details:				
OLOFT (Suspected)	400 0 Mill	Reaso		
Tablet Batch:	100.0 Mill Started:	ıgram	Daily Ora Stopped:	I
aboratory Investigations: Date Type Range	Date Tested	Result		Details



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Severe		Patient was hospitalised. 3% saline infusion.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

Tablet 200.0 Milligram Daily Oral

3atch: Started: 21/01/2001 Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking kalma, oroxine, zyprexa, temazepam.



Case Number: 161415							
Reported: 12/02/2001	Seq:	1				Gend Weig	
espitalisation:						_	ge : 29Y
Onset Date:						DC	DB:
Outcome: Recovered					С	ausali	ity: Causality possible
action Detai						1	
Preferred Term	Seve		•	Descri	ption		Treatment
ightmare		Vivid	dreams				
gitation							
ystonia						2	Zoloft ceased. started cipramil
nsomnia remor							
ledicine Details:							
OLOFT (Interaction)			Reaso	on:			
Tablet	100.0 Milligram			Daily Oral			
3atch:	Star	ted:			Stopped:		
SERZONE (Interaction)			Reaso				
Tablet		300.0 Milli	gram	Daily		Oral	
3atch:	Star	ted:			Stopped:		
aboratory Investigation		Date Tested	Result				Details



THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 161417 Reported: 12/02/2001 Iospitalisation: Onset Date:			Gender: M Weight: Age: 80Y DOB: Causality: Causality possible			
Outcome: Not yet rece eaction Detai	overed		Ca	usanty: Causanty possible		
Preferred Term	Severity	Repor	t Description	Treatment		
Aphasia		- 1	 	Zoloft ceased.		
Medicine Details: ZOLOFT (Suspected)		Reas	on:			
Tablet	50.0 Mil	ligram	Daily	Oral		
_aboratory Investigatio	one:					
Date Type	Range Date Tested	Result		Details		
Additional Information	:					
port Run 27/07/200 03:30PN	Database: pusime	P	ADRS004	Page 427 of 591		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100000000000000000000000000000000000000		-	
Preferred Term	Severity	Report Description	Treatment
Oedema		Pedal oedema - moderately severe.	
Hypoproteinaemia			

Medicine Details:

RISPERIDONE (Suspected)	;	Reason:	
	2.0 Milligram	Daily	
3atch:	Started: 03/02/2000	Stopped:	CONTIN
TEMAZEPAM (Suspected)	;	Reason:	
	20.0 Milligram	Daily	
3atch:	Started: 03/02/2000	Stopped:	
ZOLOFT (Suspected)	;	Reason:	
	50.0 Milligram	Daily	
3atch:	Started: 01/01/2000	Stopped:	

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

		ā.	
Preferred Term	Severity	Report Description	Treatment
Thinking abnormal		Thought disorder	Required a visit to doctor.

Medicine Details:

RISPERDAL (Suspected)

1.0 Milligram Daily

3atch: 3tarted: 25/12/2000 3topped: 25/01/2001

ZOLOFT (Suspected) Reason:

50.0 Milligram Daily

3atch: 3tarted: 24/10/2000 3topped: 25/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking aldactone, astrix, lanoxin, lasix. patient recovered 28/1/01.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal		_	
Preferred Term	Severity	Report Description	Treatment
Aggression			Cessation of drugs, patient hospitalised
Thinking abnormal		Thought disorder	

Medicine Details:

RISPERDAL (Suspected) Reason:

2.0 Milligram Daily

3atch: 3tarted: 12/02/2000 3topped: 20/01/2001

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 19/10/2000 3topped: 20/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking fosamax, augmentin forte, astrix.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			Stop zoloft.

Medicine Details:

ZOLOFT (Suspected)		Reason:	Depression	
	50.0 Milligram	Daily		
3atch:	Started: 27/10/2000		Stopped:	18/11/2000
TIMENTIN (Suspected)		Reason:	Agranulocyto	sis
	12.4 Gram	Daily		
3atch:	Started: 04/11/2000		Stopped:	23/11/2000
ACICLOVIR (Suspected)		Reason:		
	150.0 Milligram	Daily		
3atch:	Started: 08/11/2000		Stopped:	23/11/2000

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

	detion betai			
	Preferred Term	Severity	Report Description	Treatment
Т	remor		Both hands, worse on initiation of activities.	
Ir	nsomnia		Frequrent awakenings during the night.	
	iarrhoea		Loose bowels.	
H	leadache		Tension type over whole head, worse	
F	latulence			

Medicine Details:

ZYBAN SR (Suspected)	Reas	son:	Smoker	
	2.0 Dose Unspecified	Daily		
3atch:	Started: 01/02/2001		Stopped:	CONTIN
ZOLOFT (Suspected)	Reas	son:	Depression	
	50.0 Milligram	Daily		
3atch:	Started: 01/02/2000		Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking norvasc, matrilix, avapro and colofac. sequelae: still smokes 4 cigerettes 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.



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

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 Detai

todotion Botai			
Preferred Term	Severity	Report Description	Treatment
Glaucoma			Reduced zoloft to 25mg every second day.

Medicine Details:

MINITRAN (Other drug)		Reason:
Cream	0.0	Transdermal
3atch:	Started:	Stopped:
ZOLOFT (Suspected)		Reason: Depression
Tablet	25.0 Milligram	Daily Oral
3atch:	Started:	Stopped:

Laboratory Investigations:

	1				
Date	Туре	Range	Date Tested	Result	Details
	Other data			One eye 24 and the other eye 18 asymptomatic.	

Additional Information:



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

Report Detail	Re	ро	rt C	Deta	il
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Case Number: 161855 Seq: 1 Gender: M
Reported: 23/02/2001 Weight:
Hospitalisation: Age: 55Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

104041011 20441			-
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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking lasix, diabex, adalat.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 161856	Seq: 1	Seq: 1 Gender: F				
Reported: 23/02/20				Weight:		
ospitalisation:				Age : 47Y		
Onset Date: 01/09/20	00			DOB:		
Outcome: Not yet re	ecovered		Са	usality: Causality possible		
eaction Detai						
Preferred Term	Severity	Repo	t Description	Treatment		
remor		Very jittery tense	hands			
Agitation						
Anxiety						
Chest pain						
lushing						
lypertension				Ceased zoloft		
alpitations						
Medicine Details: ZOLOFT (Suspected)		Reas	•			
Tablet	50.0) Milligram	1 time	Oral		
3atch:	Started:		Stopped:			
aboratory Investiga		pated Deput		Details		
Date Type	Range Date Te	ested Result		Details		
Additional Informatio	on:					
ort Run 27/07/200 03:30P	N Database: pusime⊢	ļ	ADRS004	Page 435 of 591		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Speech disorder		Developed a stutter	

Medicine Details:

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

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	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.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 161888	Seq: 1		Gei	nder: M
Reported: 26/02/2001			We	eight: 64.00
spitalisation:				Age: 71
Onset Date: 01/02/2001				DOB : 03/09/1929
Outcome: Recovered			Caus	ality: Causality possible
action Detai		1		1
Preferred Term	Severity		t Description	Treatment
uscle spasms		Leg/calf cramps &	main diacconcheur of	Zoloft ceased, required a visit to doctor.
yperhidrosis ausea				
ledicine Details:				
OLOFT (Suspected)		Reas	on:	
	0.0)		
3atch:	Started:			
aboratory Investigatio	DNS: Range Date Te	ested Result		Details
additional Information	:			
ort Run 27/07/200 03:30PN	Database: pusime	А	DRS004	Page 437 of 591



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

Re	no	rt	D	eta	i
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 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction			Zoloft dropped to lower dose.
Rash maculo-papular			

Medicine Details:

ZOLOFT (Suspected) Reason:

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking tofranil, ogen and provera.



port Detail				
ase Number: 162233 Reported: 05/03/20 spitalisation:	•			Gender: F Weight: Age: 50Y
Onset Date:				DOB:
Outcome: Recover	red		Ca	usality: Causality possible
ection Detai				<u>+</u>
Preferred Term	Severity	Report	Description	Treatment
icide attempt				Ceased zoloft.
edicine Details:				
DLOFT (Suspected)		Reaso	n:	
Tablet	100			Oral
3atch:	Started:	,,,,	Stopped:	
			, pp	
boratory Investiga	ations:			
Date Type		Tested Result		Details
lditional Informati	on:			



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion			Patient was hospitalised.

Medicine Details:

Medicine Details.			
TEGRETOL (Interaction)		Reason:	
Tablet	0.0	Oral	
Зatch:	Started:	Stopped:	
ZOLOFT (Interaction)		Reason:	
Tablet	50.0 Milligram	Daily Oral	
3atch:	Started: 01/11/2000	Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Cough			Date of recovery 13/03/2001. required several visits to

Medicine Details:

MICROVAL (Other drug) Reason: Contraception

1.0 Dose Unspecified 1 time

3atch: 3tarted: 01/01/1999 **3topped:** CONTIN

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 05/10/2000 3topped: 15/02/2001

Laboratory Investigations:

Date	Туре	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.

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Case Number: 162583 Seq: 1	Case Numb					
Onset Date: Outcome: Not yet recovered Causality: Causality possible section Detail Preferred Term Severity Report Description Treatment Slaucoma Preferred Term Severity Report Description Treatment Slaucoma Preferred Term Severity Report Description Preferred Term Preferred	Reporte	ed: 09/03/2001	Seq: 1		We	eight:
Outcome: Not yet recovered Severity Report Description Treatment Preferred Term Severity Report Description Treatment Slaucoma Medicine Details: ZOLOFT (Suspected) Reason: Depression Tablet 25.0 Milligram Daily Oral 3atch: Started: STERM Report Description Teacher CONTIN	-					
Preferred Term Severity Report Description Treatment Slaucoma Medicine Details: ZOLOFT (Suspected) Tablet 25.0 Milligram Daily Oral Batch: Started: STERM Stopped: CONTIN						
Preferred Term Severity Report Description Treatment Blaucoma Continued			erea		Caus	ality: Causality possible
Medicine Details: ZOLOFT (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: Started: STERM Stopped: CONTIN			Severity	Report Des	crintion	Treatment
Medicine Details: ZOLOFT (Suspected) Reason: Depression Tablet 25.0 Milligram Daily Oral 3atch: Started: STERM Stopped: CONTIN		circa reiiii	Ocventy	report Des	Сприоп	Treatment
Tablet 25.0 Milligram Daily Oral 3atch: Started: STERM Stopped: CONTIN aboratory Investigations:						
Tablet 25.0 Milligram Daily Oral 3atch: Started: STERM Stopped: CONTIN aboratory Investigations:						
Tablet 25.0 Milligram Daily Oral 3atch: Started: STERM Stopped: CONTIN aboratory Investigations:						
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Tablet 25.0 Milligram Daily Oral 3atch: Started: STERM Stopped: CONTIN aboratory Investigations:						
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Date Type Range Date Tested Result Details						
				d Result		Details



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

Report I	Detail
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 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Sodium level of 120	
Anorexia			
Weight decreased			Withdrew zoloft and restricted

Medicine Details:

ZOLOFT (Suspected) Reason:

0.0

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Suspect that patient had an inappropriate adh secretion due to zoloft.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 16281 Reported: 19/03/ ospitalisation: Admitt Onset Date: Outcome: Recoveraction Detai Preferred Term Paraesthesia Hot flush Hyperhidrosis Palpitations Medicine Details: ZOLOFT (Suspected) Tablet 3atch:	2001 ted to hospital rered	verity	rning sensation	t Description n on her body.	Weight: Age: DOB: Causality: Causality possible Treatment Patient was hospitalised.
Onset Date: Outcome: Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoverance Recoveran	vered Sev	Bui	rning sensation	t Description n on her body.	DOB: Causality: Causality possible Treatment
Outcome: Recoveraction Detail Preferred Termoraraesthesia of flush operhidrosis alpitations edicine Details: COLOFT (Suspected) Tablet	n Sev	Bui	rning sensation	t Description n on her body.	Causality: Causality possible Treatment
Preferred Term araesthesia ot flush yperhidrosis alpitations ledicine Details: ZOLOFT (Suspected) Tablet	n Sev	Bui	rning sensation	t Description n on her body.	Treatment
Preferred Term araesthesia ot flush yperhidrosis alpitations ledicine Details: ZOLOFT (Suspected) Tablet		Bui	rning sensation	n on her body.	
araesthesia ot flush yperhidrosis alpitations dedicine Details: ZOLOFT (Suspected) Tablet		Bui	rning sensation	n on her body.	
edicine Details: COLOFT (Suspected) Tablet	3t		Reas		Patient was hospitalised.
yperhidrosis alpitations ledicine Details: zoloft (Suspected) Tablet	3t	50.0 M		on:	Patient was hospitalised.
ledicine Details: ZOLOFT (Suspected) Tablet	St	50.0 M		on:	
ledicine Details: ZOLOFT (Suspected) Tablet	31	50.0 M		on:	
ZOLOFT (Suspected) Tablet	3t	50.0 M		on:	
ZOLOFT (Suspected) Tablet	St	50.0 M		on:	
COLOFT (Suspected) Tablet	St.	50.0 M		on:	
OLOFT (Suspected) Tablet	St	50.0 M		con:	
OLOFT (Suspected) Tablet	St	50.0 M		con:	
ZOLOFT (Suspected) Tablet	3t	50.0 M		son:	
Tablet	3t	50.0 M		on:	
	3t	50.0 M			
3atch:	3t		illigram	Daily	Oral
		uitou.		Stopped:	
.aboratory Investig	gations:	Date Tested	I Result		Details
- 5.10			1 1100000		



		ille,Aydep,2020l					
Report Det	ail						
Case Numbe	er: 162815	Seq:	1			Gender:	F
Reporte	ed: 19/03/200	_				Weight:	
Iospitalisatio						Age:	45Y
Onset Dat						DOB:	
Outcom	ne: Recovere	d				Causality:	Causality possible
eaction De		<u> </u>				1	
	erred Term	Sev	erity	Repor	Description		Treatment
Serotonin syn	drome					Zolo	ft ceased.
Medicine D				Reas	on: Depression		
Tablet			50.0 Milli		1 time	Oral	
3atch:		Sta	irted:		Stopped:		
Laboratory							
Date	Туре	Range	Date Tested	Result		Deta	ils



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

Report D)etail
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Case Number: 162816 Seq: 1 Gender: F
Reported: 19/03/2001 Weight:
Hospitalisation: Age: 40Y

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Syncope		Vasovagal reaction the next morning.	

Medicine Details:

Medicine Details.					
MICARDIS (Other drug)			Reason:		
Tablet	0.0	0.0		Oral	
3atch:	Started:		Stopped:		
ZOLOFT (Suspected)			Reason:		
Tablet	25.0	Milligram	Daily	Oral	
3atch:	Started:		31	topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient had a history of vasovagal reactions.



DOB: 17/05/1948

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

Outcome: Recovered Causality: Causality possible

Reaction Detai

Onset Date: 22/12/2000

Veaction Detai	-		
Preferred Term	Severity	Report Description	Treatment
Depersonalisation		"out of body " experience.	
Anxiety			
Pruritus			Sertraline ceased. given phenergan and diazepam.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 20/12/2000 3topped: 22/12/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Known to have had previous allergies before. patient also taking - abacavir, stavudine, nelfinavir, loperamide and temazepam.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion botal		E	
Preferred Term	Severity	Report Description	Treatment
Diarrhoea		20 motions (watery)/day	
Rectal haemorrhage			Zoloft ceased. date of recovery 09/03/01.

Medicine Details:

3atch:

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

07/03/2001

Stopped:

3tarted: 28/02/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking betaloc, stelazine, tritace, li co3.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

icaction Betai	_		
Preferred Term	Severity	Report Description	Treatment
Yawning	Severe		Changed drug, another ssri was given and this side effect was considerably less with the new drug. required a visit to

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

1.0 Dose Unspecified Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



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

Report Detail

Case Number:163073Seq: 1Gender:FReported:22/03/2001Weight:Hospitalisation:Admitted to hospitalAge: A8

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Pain		Generalised pain	
Abdominal pain			
Atrial fibrillation			
Consciousness fluctuating			
Diarrhoea			Patient hospitalised and given
Hypoglycaemia			
Hyponatraemia			
Nausea			
Shock			
Vomiting			

Medicine Details:

SERTRALINE HYDROCHLO	ORIDE (Interaction)	Reason:	Depression	
Tablet	0.0		•	Oral
3atch:	Started:		Stopped:	
ARICEPT (Interaction)		Reason:	Presenile deme	ntia
Tablet	10.0 Millio	gram Daily	•	Oral
3atch:	Started:		Stopped:	16/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Albumin		16/03/2000	32	
	Creatine kinase Electrocardiograph		16/03/2000	70	Ecg - initial sinus bradycardia, then rapid atrial fibrilation.
	Other data				Thyroid function test - 0.4
	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 comlex, pericyazine, haloperidol.

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

Report Detail

Case Number:163073Seq: 1Gender:FReported:22/03/2001Weight:Hospitalisation:Admitted to hospitalAge: A8

Onset Date: DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

Medicine Details:

SERTRALINE HYDROCHLO	RIDE (Interaction)	Reason:	Depression	
Tablet	0.0			Oral
3atch:	Started:		Stopped:	
ARICEPT (Interaction)		₹eason:	Presenile den	nentia
Tablet	10.0 Milligra	m Daily	,	Oral
3atch:	Started:		Stopped:	16/03/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium		16/03/2000	155	After admission 129

Additional Information:

Patient also taking ranitidine, folic acid, pancrease, vitamin b comlex, pericyazine, haloperidol.



Seq:	1		Ger	nder: F
				ight:
				Age: 40Y DOB:
				ality: Causality possible
			Guusi	unity. Caddanty possible
Sev	verity	Report	t Description	Treatment
				Dapa-tabs ceased and efficac of zoloft returned.
	• •	Reas		
34				
Started:				
	0.0		Oral	
3t	arted:		Stopped:	
	Date Tested	Result		Details
	Date Tested	Result		Details
	31		Reason 0.0 Started:	Report Description Reason: 0.0 Oral Started: Stopped: Reason: 0.0 Started: Stopped: Reason: 0.0 Oral Started: Stopped:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

todotion botal			
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

3atch: 3tarted: 08/06/2000 3topped: 28/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Baby displayed facial grimacing and leg stiffness whilst mother was breast fee ding and taking zoloft. the dosage stop date is not necessarily accurate but indicates that stoppage occurred sometime during the month.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:

Reported: 29/03/2001 Weight: Hospitalisation: Age: 46

Onset Date: DOB: 09/04/1954

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Apathy			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

150.0 Milligram Daily

3atch: 3tarted: 01/01/2001 3topped:

Laboratory Investigations:

Date	Туре	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 sometim e in the month.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis			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	Туре	Range	Date Tested	Result	Details

Additional Information:

Reaction ceased with withdrawal of drug but returned after reintroduction.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

	<u> </u>	-	
Preferred Term	Severity	Report Description	Treatment
Bradykinesia			

Medicine Details:

ZOLOFT (Suspected) Reason:

25.0 Milligram Daily

3atch: 3tarted: 17/03/2001 3topped: 20/03/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking madopar, ditropan, solprin, lipitor. patient recovered 29/3/01. known parkinsons disease.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Bota.	Addition Bottan								
Preferred Term	Severity	Report Description	Treatment						
Grand mal convulsion			Patient was hospitalised. zoloft ceased. a neurologist has put the patient on anticonvulsant						
Headache									

Medicine Details:

PARACETAMOL (Other drug)		Reason: Migraine	
Tablet	1.0 Dose Unspe	ecified As necessary Oral	
Зatch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	75.0 Milligram	Daily Oral	
Batch:	Started:	Stopped:	7W

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The patient has no history of seizure but does have a history of migraines.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Acne			Required a visit to doctor. zoloft ceased, date of recovery:

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

200.0 Milligram Daily

3atch: 3tarted: 04/10/2000 3topped: 23/01/2001

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Dotai			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		J	Patient hospitalised icu admission. date of recovery

Medicine Details:

PANADEINE FORTE (Other drug)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
DI-GESIC (Other drug)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
Oral application	150.0 Microgram	Daily	Oral
Зatch:	Started:	Stopped:	
SERTRALINE HYDROCHLORIDE (Susp	ected)	Reason:	
Oral application	50.0 Milligram	Daily	Oral
3atch:	3tarted: 28/03/2001	Stopped:	03/04/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium		03/04/2001	106MMOL/L	

Additional Information:

Recently commenced on sertraline 50mg daily. no previous exposure to it.



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

Report Detail							
Case Number: Reported: Hospitalisation: Onset Date:	17/04/2001 Admitted to hosp 03/04/2001 Recovered	Seq: ital	1				60.00
Medicine Deta					Reason:		
3atch:		3ta	400.0	Milligram	Daily	Stopped:	
Laboratory In	vestigations:						
Additional Information: Recently commenced on sertraline 50mg daily. no previous exposure to it.							

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

Report	Detail
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Hypertension			

Medicine Details:

DIAZEPAM (Other drug)		Reason: Anxiety neurosis
	1.0 Dose Unsp	pecified As necessary
3atch:	Started:	Stopped:
MONOPRIL (Suspected)		Reason: Essential benign hypertension
	10.0 Milligram	Daily
3atch:	Started:	Stopped:
ZOLOFT (Suspected)		Reason: Depression
	50.0 Milligram	Daily
3atch:	Started:	Stopped:
TRAMAL (Suspected)		Reason: Other disturbance of sensation
	150.0 Milligram	Daily
3atch:	Started: 23/03/2001	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Report Detail		
Case Number: 163893 Reported: 23/04/2001 Hospitalisation: Admitted to hosp Onset Date: Outcome: Recovered Reaction Detai	Seq: 1	Gender: U Weight: Age: DOB: Causality: Causality possible
Medicine Details: CELEBREX (Suspected)	₹eas	
3atch:	100.0 Milligram Started: 14/11/2000	Daily Stopped:
Laboratory Investigations:		
Additional Information:		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal		_	
Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis			Patient was hospitalised, fluids, monitoring. date of recovery: 24/4/2001.

Medicine Details:

SODIUM VALPROATE (Suspected)		Reason: Unspecifid affective psychosis
	1.0 Gram	Daily
3atch:	3tarted: 01/09/2000	3topped: 18/04/2001
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
	10.0 Milligram	Daily
3atch:	Started: 01/09/2000	Stopped: 18/04/2001
SERTRALINE HYDROCHLORIDE (Sus	pected)	Reason: Unspecified schizophrenia
	50.0 Milligram	Daily
3atch:	Started: 01/09/2000	Stopped: 18/04/2001

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion botal		_	
Preferred Term	Severity	Report Description	Treatment
Failure to thrive		Failure to thrive	Hospitalised at 7 months
Vomiting neonatal			
Weight decreased			

Medicine Details:

ZOLOFT (Suspected)

Reason:

200.0 Milligram Daily Breast milk transfer

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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 Zoloft 200mg/daily. The mother took zoloft 100mg/daily during pregnancy. The baby has been hospitalised today due to failure to thrive and vomiting. Besides Zoloft, the mother is not receiving any other medication. It is unknown whether the baby is receidving any other medication or has other medical illnesses.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

caction Betai			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Haloperidol. lasix and zoloft ceased. pt hospitalised

Medicine Details:

TRANSIDERM-NITRO (Other drug)		Reas			
		0.0			
Batch:	Started:	12/01/2001	:	Stopped:	
LANOXIN PG (Other drug)		Reas	son:		
Oral application		2.0 Dose Unspecified	Daily		Oral
Batch:	Started:	12/01/2001	:	Stopped:	
NORVASC (Other drug)		Reas	son:		
Tablet		2.5 Milligram	Daily		Oral
Batch:	Started:	12/01/2001	:	Stopped:	
CHLORVESCENT (Other drug)		Reas	son:		
Oral application		2.0 Dose Unspecified	Daily		Oral
Batch:	Started:	12/01/2001	:	Stopped:	12/01/2001

Laboratory Investigations:

	Date	Туре	Range	Date Tested	Result	Details
Ī		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:



Report Detail

Case Number: 164212

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Gender: F

Reported:	03/05/2001					Weight:		
spitalisation:	Admitted to hospital	l				Age:	88	
Onset Date:	09/02/2001					DOB:	11/04/1912	
Outcome:	Recovered				C	Causality:	Causality poss	ible
action Detai								
edicine Deta	ails:							
ASIX (Suspected				Reason:				
Oral applica	ation		1.0 Dose Unspeci	ified Daily		Oral		
3atch:		Started:	12/01/2001		Stopped:	09/02/2001		
OLOFT (Suspect	ed)			Reason:				
Tablet		2	25.0 Milligram	Daily		Oral		
3atch:			01/02/2001		Stopped:	09/02/2001		
aboratory In	vestigations:							
dditional Inf	ormation:							
ort Run 27/07/200	03:31PN Databas	e: pusime		ADRS004			Page 466	of 591



Report Detail						
Case Number:	164301	Seq:	1		Gen	der: F
Reported: (7/05/2001				Wei	ght: 46.00
Hospitalisation:					Į.	Age: 43
Onset Date: (01/12/2000				D	OB : 19/03/1957
Outcome: 1	Not yet reco	vered			Causa	lity: Causality possible
Reaction Detai		+				
Preferred	Term	Seve	erity	Report	Description	Treatment
Nausea						Required a visit to doctor
Somnolence						
Medicine Deta				Reaso	on:	
202011 (00000000	-,		50.0 Milli		Daily	
3atch:		3ta	rted: 01/11/20		Stopped:	
Laboratory Inv	rootigatio					
Laboratory Inv	ype	Range	Date Tested	Result		Details
Date	700	runge	Date 1 Coled	rtoduit		Solumo
Additional Info	ormation:					



Case Number: 164345 Reported: 07/05/2001 ospitalisation: Onset Date: Outcome: Recovered		Seq	: 1	Gender: M Weight: Age: 64Y DOB: Causality: Causality probable			
action [Pr	Detai eferred Term	Se	verity	Repo	rt Description	Treatment	
	on abnormal		10.1.5				
Extrapyramidal disorder						Sertraline ceased.	
	Details:			Reas	son:		
3ato	sh.	2	0.0 tarted:		Stopped:		
	PRIM-SULFAMETHOX			Reas			
		-	0.0				
3ato		31	tarted:		Stopped:		
CLARITHRO	OMYCIN (Other drug)		0.0	Reas	son:		
Batch:		3	tarted:		Stopped:		
ITRACONAZOLE (Other drug)		Reason:					
IIRACONA			0.0				
		_	tarted:		Stopped:		
3ato	:h:	3					
3ato	ry Investigatio	ns:	Data Tastad	Poor!	T	Dotaile	
3atc			Date Tested	Result	Large hepatic mitochor I-lactic acidosis and hig	Details ndrial dna deletions associated with ghly active antiretroviral therapy.	



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Hospitalisation: Onset Date: Outcome: Reaction Detai	07/05/2001 Recovered	Seq: 1			Gender: Weight: Age: DOB: Causality:	
Medicine Deta		drug\		Joseph .		
WIEAILETINE HYDE	ROCHLORIDE (Other	urug)	0.0	Reason:		
Dotah.		24	0.0		Stopped:	
3atch:	ROCHLORIDE (Susp	Started	u.	Reason:	Stopped:	
SENTRALINE HYD	MOOHLOKIDE (Susp	ecieu)	0.0	veasuii.		
3atch:		Started			Stopped:	
Laboratory In	vestigations:					
Additional Inf Aids2001, vol 15 n						



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104041011 20441		-	
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				
3atch:	Started: 07/04/1997	Stopped:	03/05/2001			
SEROQUEL (Suspected)		Reason:				
Oral application	400.0 Milligram	Daily	Oral			
3atch:	Started: 29/11/2000	Stopped:	03/05/2001			
ZOLOFT (Suspected)		Reason: Anxiety neuro	osis			
	100.0 Milligram	Daily				
3atch:	Started: 23/03/1999	Stopped:	03/05/2001			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

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 Detai

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

2.0 Dose Unspecified Daily

3atch: Started: Stopped:

ZOLOFT (Suspected) Reason: Depression

25.0 Milligram Daily

3atch: 3tarted: 26/04/2000 3topped: 02/05/2000

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Report D)etail
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 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 Detai

Preferred Term	Severity	Report Description	Treatment
Agitation		Extreme agitation felt he was "going loopy"	Zoloft ceased. date of recovery 30/09/2001.

Medicine Details:

MEGICINE DETAILS.						
STILNOX (Other drug)	Reason:					
	10.0 Milligram	Daily				
3atch:	Started:	Stopped:				
ZOLOFT (Suspected)		Reason: Depression				
Tablet	50.0 Milligram	Daily	Oral			
3atch:	Started: 27/04/2001	Stopped:	28/04/2001			

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Aggression			Zoloft ceased.

Medicine Details:

Medicine Details.			
PARACETAMOL (Other drug)		Reason:	
Tablet	0.0	Oral	
3atch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
	50.0 Milligram	Daily	
3atch:	Started: 30/07/1999	Stopped:	

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Zoloft ceased. fluid restriction

Medicine Details:

GLIPIZIDE (Other drug)		Reas	on:	Diabetes melli	tus
	40.0	Milligram	Daily		
3atch:	Started:	L TERM		Stopped:	
MAXOR (Other drug)		Reas	on:	Other disease	s of esophagus
Capsule	20.0	Milligram	Daily		Oral
3atch:	Started:	L TERM		Stopped:	
DISPRIN (Other drug)		Reas	on:	Prophylaxis	
DISPRIN (Other drug)	150.0		on: Daily	Prophylaxis	
DISPRIN (Other drug) 3atch:	150.0 Started:			Prophylaxis	
		Milligram	Daily	, ,	
3atch:		Milligram L TERM	Daily	Stopped:	Oral

Laboratory Investigations:

Date	Туре	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	



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

	Seq: 1			Gender:	Г	
Reported: 24/05/2001				Weight:		
ospitalisation:				Age:	82	
Onset Date:				DOB:	08/07/1918	
Outcome: Recovered			C	ausality:	Causality probab	le
eaction Detai						
Medicine Details:						
PERINDOPRIL (Other drug)		Reason:				
	4.0 Milligram					
Batch:	Started:	L TERM	Stopped:			
ZOLOFT (Suspected)		Reason:	Depression			
	c- c					
	25.0 Milligram	Daily				
3atch:	25.0 Milligram Started: 03/11/2000	Daily	Stopped:	09/03/2001		
3atch:		Daily	Stopped:	09/03/2001		
3atch:		Daily	Stopped:	09/03/2001		
3atch:		Daily	Stopped:	09/03/2001		
3atch:		Daily	3topped:	09/03/2001		
3atch:		Daily	Stopped:	09/03/2001		
3atch:		Daily	3topped:	09/03/2001		
	Started: 03/11/2000	Daily	3topped:	09/03/2001		
	Started: 03/11/2000	Daily	₹topped:	09/03/2001		
	Started: 03/11/2000	Daily	₹topped:	09/03/2001		
	Started: 03/11/2000	Daily	3topped:	09/03/2001		
	Started: 03/11/2000	Daily	₹topped:	09/03/2001		
	Started: 03/11/2000	Daily	Stopped:	09/03/2001		
	Started: 03/11/2000	Daily	3topped:	09/03/2001		
	Started: 03/11/2000	Daily	₹topped:	09/03/2001		
	Started: 03/11/2000	Daily	Stopped:	09/03/2001		
aboratory Investigations:	Started: 03/11/2000	Daily	Stopped:	09/03/2001		
Jatch: Laboratory Investigations: Additional Information:	Started: 03/11/2000	Daily	₹topped:	09/03/2001		
_aboratory Investigations:	Started: 03/11/2000	Daily	Stopped:	09/03/2001		
_aboratory Investigations:	Started: 03/11/2000	Daily	Stopped:	09/03/2001		
_aboratory Investigations:	Started: 03/11/2000	Daily	Stopped:	09/03/2001		



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Hypertonia		1 5 5	Zoloft reduced and ceased. required a visit to doctor.

Medicine Details:

LISINOPRIL (Other drug)			Reason:	Essential benign hypertension	
	20.0	Milligram	Daily		
3atch:	Started:		L TERM	Stopped:	
CARDIPRIN 100 (Other drug)			Reason:	Chron isch heart dis no hyper	
	50.0	Milligram	Daily		
3atch:	Started:		L TERM	Stopped:	
NORVASC (Other drug)			Reason:	Chron isch heart dis no hyper	
NORVASC (Other drug)	10.0	Milligram	Reason: Daily	Chron isch heart dis no hyper	
NORVASC (Other drug) 3atch:	10.0 3tarted:	3 -		Chron isch heart dis no hyper Stopped:	
5 ,		3 -	Daily	21	
3atch:			Daily L TERM	21	

Laboratory Investigations:

Date	Туре	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.

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

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 Detai

Medicine Details:

Medicine Details.					
PERSANTIN SR (Other drug)		Reason:	Prophylaxis		
	200.0 Milligra	m Daily	,		
Зatch:	Started:	L TERM	Stopped:		
ZOLOFT (Suspected)		₹eason:	Depression		
	150.0 Milligra	m Daily	,		
3atch:	3tarted: 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.

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

 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 Detai

todotion Dotal			
Preferred Term	Severity	Report Description	Treatment
Convulsion			Sertraline ceased. date of recovery 10/01/01.

Medicine Details:

DONEPEZIL HYDROCHLORIDE (Oth	ner drug)	Reason:	Presenile den	nentia
Oral application	10.0 Milligram	Daily		Oral
3atch:	Started:		Stopped:	
RISPERIDONE (Other drug)		Reason:	Otr spec symp	p psychopathol nec
Oral application	1.0 Milligram	Daily		Oral
3atch:	Started: 14/11/2000		Stopped:	
SERTRALINE HYDROCHLORIDE (S	uspected)	Reason:	Depression	
Tablet	50.0 Milligram	Daily		Oral
3atch:	Started: 05/12/2000		Stopped:	10/01/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hypotension	Life		Required aramine infusion intraoperatively and post op for 2 days to maintain bp (laparotomy). date of recovery:

Medicine Details:

ZOTON (Other drug)		Reason:	Other diseases of esophagus
	0.0		
Зatch:	Started:		Stopped:
CALTRATE (Other drug)		Reason:	
	0.0		
3atch:	Started:		Stopped:
PHYTOMENADIONE (Other drug)		Reason:	
	0.0		
Зatch:	Started:		Stopped:
		_	
OROXINE (Other drug)		Reason:	
OROXINE (Other drug)	0.0	Reason:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking hrt.



Report Detail							
Hospitalisation: Onset Date:	25/05/2001 15/05/2001 Recovered	Seq: 1			C	Gender: F Weight: 70.00 Age: 50 DOB: 23/11/1950 causality: Causality p	
Medicine Deta	ails: PROCHLORIDE (Susp	ected)		₹eason:	Depression		
OLIVINALINE III	MOOFILORIDE (Odsp	ecteu	0.0	ved5011.	Бергеззіоп		
3atch:		Started	l:		}topped:	15/05/2001	
ENALAPRIL MALE	ATE (Suspected)			Reason:	Essential ben	ign hypertension	
			40.0 Milligr	am Daily			
Зatch:		Started	l:		Stopped:	15/05/2001	
Laboratory In							
	vestigations:						



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

3atch: Started: Stopped: CONTIN

Laboratory Investigations:

Date	Туре	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.

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Agitation			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started: 01/11/2000

Stopped:

Laboratory Investigations:

Date	Туре	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.

Report Run 27/07/200 03:31PN Database: pusime ADRS004 Page 482 of 591



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

Report Deta	ı	ı
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Case Number: 164979 Seq: 1

Reported: 16/05/2001

Hospitalisation:

Age: AD

Onset Date: 25/12/1999 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

<u> </u>			
Preferred Term	Severity	Report Description	Treatment
Hypokinesia		Delayed in motor development.	
Coordination abnormal			
Neonatal disorder			
Tremor			

Medicine Details:

PREDNISONE (Suspected)		Reason:	Systemic lupus erythematosus	
	0.0			
3atch:	Started:		Stopped:	
NARCOTIC NOS (Suspected)		Reason:	Pain	
	0.0			
3atch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	Depression	
Tablet	200.0 Milligram	Daily	y Oral	
3atch:	Started:		Stopped:	

Laboratory Investigations:

Date	Туре	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.



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

Report Detail

Case Number:164998Seq: 1Gender:FReported:30/05/2001Weight:0.00Hospitalisation:Admitted to hospitalAge: 15Y

Onset Date: 31/12/1999 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

100000000000000000000000000000000000000		-	
Preferred Term	Severity	Report Description	Treatment
Bipolar disorder		Manic depressive psychosis	
Agitation			

Medicine Details:

ZOLOFT (Suspected)

Season: Depression

50.0 Milligram Daily Oral

Batch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 27/07/1997
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detail

104011011 20141			
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

3atch: 3tarted: 01/03/1997 3topped: 31/07/1997

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104011011 20141			-
Preferred Term	Severity	Report Description	Treatment
Agitation			
Hyperhidrosis			Zoloft and valium ceased.

Medicine Details:

VALIUM (Other drug)		Reason:	
Oral application	0.0	Oral	
3atch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	0.0	Oral	
3atch:	Started:	Stopped: 2M	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Previous exposure to zoloft in 1995 produced same reaction.



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

Repor	t Detail
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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 Detai

todotion Botai			<u> </u>
Preferred Term	Severity	Report Description	Treatment
Urticaria			Zoloft ceased. treated with aristocort 0.02% and claratyne 1 daily. required a visit to

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

3atch: Started: 21/05/2001 Stopped: 30/05/2001

ZYBAN SR (Suspected) Reason: Smoker

2.0 Dose Unspecified Daily

3atch: 3tarted: 21/05/2001 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

 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 Detai

touction Botal			
Preferred Term	Severity	Report Description	Treatment
Crying			Required a visit to doctor.
Mania			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Took about 6 weeks to recovery.



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

Report Do	etail
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Dysphagia			

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Tablet	0.0	Daily Ora	al
Зatch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily Ora	al
3atch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Past history - brain injury.



Seq: 1			der: F ght:
			Age: 53Y
			OB:
ered		Causa	ality: Causality possible
0	Danada	December Com	Totalogue
	•	•	Treatment
	assing blood in uri	ne.	
3tarted: 18/0	6/1998	3topped: 18/08	8/2000
S:	od Doout		Dataila
Range Date Test	ed Result		Details
1			_
	Severity P 50.0 Started: 18/0	Report I Passing blood in uri Reasor 50.0 Milligram Started: 18/06/1998	Report Description Passing blood in urine. Reason: 50.0 Milligram Daily Oral Started: 18/06/1998 Stopped: 18/06



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

Case Number:165375Seq:1Gender:MReported:07/06/2001Weight:Hospitalisation:Admitted to hospitalAge:

Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient was hospitalised

Medicine Details:

MEGICINE DELANS.					
ZOLOFT (Suspected)		Reas	on:		
Tablet	600.0	Milligram	Total	Oral	
3atch:	Started:			Stopped:	
NALTREXONE HYDROCHLORID	Reas	on:			
Tablet	20.0	Dose Unspecified	Total	Oral	
3atch:	Started:			Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also had 15 schooners of beer.



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

Report	Detail
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 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 Detai

Cachon Detai	Saction Detail							
Preferred Term	Severity	Report Description	Treatment					
Coma								
Convulsion								
Encephalopathy								
Sudden death								

Medicine Details:

CESIUM CHLORIDE (Interaction)		Reason:
	0.0	
3atch:	Started: 31/05/2001	Stopped:
ZOLOFT (Interaction)		Reason:
	0.0	
3atch:	Started:	Stopped:
MAXOLON (Interaction)		Reason:
	0.0	Oral
3atch:	Started:	Stopped:
TEMAZEPAM (Interaction)		Reason:
	0.0	Oral
3atch:	Started:	Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient thought to have serotonin encephalopathy, no evidence of 2nd ca on ct or mri.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Report Iospitalisatio Onset Da	ner: 165514 ed: 01/06/2001 ne: Admitted to ate: 17/02/2001 ne: Recovered	hospital	1			DOB:	49Y
eaction De						Causanty.	Causality possible
	erred Term	Sev	erity	Repor	t Description		Treatment
Epistaxis						pation pac	ent was hospitalised. ent required cautery and king on 3 different assions. ceased celebrex.
Hypertension	1						
Medicine [Details:						
TEMAZE (Oth				Reas	on:		
			0.0				
3atch:		3ta	arted: 02/07/19		Stopped:		CONTIN
CELEBREX (S			200.0 Milli	Reas	on: Daily	Oral	
3atch:		Sta	arted: 05/06/20	_	Stopped:		1
	HYDROCHLORIDE			Reas		, 02, 200	
Tablet				e Unspecified		Oral	
3atch:	:	Sta	arted: 10/05/20)00	Stopped:		CONTIN
	y Investigatio		I Date Tarked I	Possiti.		Dut	
Date	Туре	Range	Date Tested	Result		Deta	alis
Additional	Information	:					



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

1	teaction Detai			
	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

 3atch:
 3tarted:
 01/11/1999
 \$topped:
 06/06/2001

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

caction betain							
Preferred Term	Severity	Report Description	Treatment				
Rash erythematous		Erythematous lumps on lower legs.					
Hyperhidrosis		Night sweats					
Oedema		Swelling in legs, knes and ankles.					
Fatigue							

Medicine Details:

ZOLOFT (Suspected)

Tablet

50.0 Milligram

Daily

Oral

Started: 01/11/1999

Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient started taking zoloft 50mg daily, the dose was gradually increased to 150mg daily.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

odotion botai							
Preferred Term	Severity	Report Description	Treatment				
Convulsion							
Hallucination							
Nightmare			Required a visit to doctor. zoloft ceased.				

Medicine Details:

ZOLOFT (Interaction) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 11/06/1994 3topped:

ARICEPT (Interaction) Reason:

5.0 Milligram Daily

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	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.



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

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 Detai

- 3				-
	Preferred Term	Severity	Report Description	Treatment
	Muscle spasms	Severe	· ·	Required a visit to doctor. date of recovery 26.2.01. zoloft and celebrex ceased.

Medicine Details:

ZOLOFT (Interaction)		Reason:	
	50.0 Milligram	Daily	
Зatch:	Started:	Stopp	ped:
CELEBREX (Interaction)		Reason:	
	400.0 Milligram	Daily	
Зatch:	Started:	Stopp	ped:
MODURETIC (Other drug)		Reason:	
MODURETIC (Other drug)	0.0	Reason:	
MODURETIC (Other drug) 3atch:	0.0 Started:	Reason:	ped:
, ,			ped:
3atch:		€topp	ped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Hospitalisation: Onset Date:	04/06/2001 01/02/2001 Recovered	Seq: 1						Gender: Weight: Age: DOB: Causality:	100.00 52 08/08/19	
Medicine Deta	ails:									
STEMETIL (Other	drug)			_	Reaso					
			1.0 Dos	e Unspe	ecified	As neces				
3atch:		Started:					Stopped			
PREMIA 5 CONTIN	IUOUS (Other drug)				Reaso					
Details.			1.0 Dos			Daily	M			
3atch:	d\	Started:		L	TERM		3topped:			
TENORMIN (Other	arug)	5	O O Millio	arom	Reaso					
Заtch:		ા Started:	0.0 Milli		TERM	Daily	Stopped			
ZANTAC (Other dr	ana)	Jianteu.			Reaso	ın:	topped			
ZANTAG (GINGI GI	ug <i>)</i>	30	0.0 Milli	oram	touse	Daily				
3atch:		Started:			TERM	24,	Stopped			
Laboratory In	vestigations:									
Additional Inf	formation:									



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

Report Detail

Case Number:165971Seq:1Gender:FReported:29/06/2001Weight:63.00Hospitalisation:Admitted to hospitalAge:53Y

Onset Date: 09/06/2001 DOB:

Outcome: Recovered Causality: Causality probable

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Confusional state			
Diarrhoea			
Haematemesis			
Hyperhidrosis			
Nausea			Zoloft ceased. treated with iv fluids, omeprazole and iv gentamicin. patient was
Rash			nneniialiean
Renal pain			
Vomiting			

Medicine Details:

ASPIRIN (Other drug)		Reason:	
	300.0 Milligram	Weekly	
Зatch:	Started:	Stopped:	
RAMIPRIL (Other drug)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
THYROXINE SODIUM (Other drug)		Reason:	
THYROXINE SODIUM (Other drug)	150.0 Milligram	Reason: Daily	
THYROXINE SODIUM (Other drug) 3atch:	150.0 Milligram		
, J	· ·	Daily	
3atch:	· ·	Daily 3topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Sequelae: slight dizziness persisted till 24.6.01. allergies: stemetil.



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

Report D)etail
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Congenital hand malformation			

Medicine Details:

Medicine Details.			
ZOLOFT (Suspected)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
ORAP (Suspected)		Reason:	
	0.0		
3atch:	Started:	Stopped:	

Laboratory Investigations:

Date	Туре	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.



Report Detai						
_	0 4		O a se da se			
Case Number: 166082	Seq: 1		Gender			
Reported: 03/07/2001			Weight			
ospitalisation:			Age			
Onset Date:			DOB			
Outcome: Recovered			Causality	: Causality probable		
eaction Detai Preferred Term	Severity	Renor	t Description	Treatment		
Amnesia	Ceventy	Didn't remember s		redunent		
-atigue		Excessively tired.	ncop wanting.			
Depersonalisation			ce of being "spaced out".			
Sleep walking			a dozen times over 18			
Somnolence		mappened about a	a dozen linies over 16			
Medicine Details: ZOLOFT (Suspected)		Reas	on:			
	100.	.0 Milligram Daily				
3atch:	Started:		Stopped:			
Laboratory Investigation Date Type	S: Range Date T	ested Result	Det	ails		
	ĺ					
Additional Information:						



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 hospitalAge: 33YOnset Date:28/05/2001DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Depersonalisation		"funny feeling" in head and feeling vague.	
Hypoaesthesia			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.
Convulsion		Seizure	
Amnesia			

Medicine Details:

ZOLOFT (Suspected)		Reason:	Anxiety neuro	sis
Tablet	100.0 Milligram	Daily		Oral
3atch:	Started: 01/02/2001		Stopped:	17/06/2001

Laboratory Investigations:

Date	Туре	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.

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Report Detail							
Case Number: 166326	Seq: 1				Gende	r: M	
Reported: 11/07/2001	-				Weight	t:	
Hospitalisation:					Age		
Onset Date:					DOE	3:	
Outcome: Unknown					Causality	: Causality possible	
Reaction Detai	-	_					
Preferred Term	Severity		Repor	Description		Treatment	
Ejaculation failure	Severe	Seve	ere.				
Medicine Details:							
ZOLOFT (Suspected)	Reason: Behavior disorders of childhod						
Tablet	500.0 Milligram Daily Oral						
3atch:	Started: Stopped:						
Laboratory Investigation	ns:						
Date Type		Tested	Result		De	tails	



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

Report Do	etail
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 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 Detai

todotion botal		<u>-</u>	
Preferred Term	Severity	Report Description	Treatment
Alcoholism		Experienced alcohol cravings	
Weight increased		Put on 10 kilos	

Medicine Details:

TRAMAL (Other drug)			
	0.0		
3atch:	Started:	Stopped:	
DI-GESIC (Other drug)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
	100.0 Milligram	Daily	Oral
3atch:	Started : 01/01/1999	Stopped:	15/06/2001

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		·	Plans to cease zoloft if event do not resolve
Hyperprolactinaemia			

Medicine Details:

Medicine Details.			
ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
3atch:	Started: 27/02/2001	Stopped:	15/06/2001
RISPERIDONE (Suspected)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
3atch:	Started:	L TERM Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details	
	Prolactin				Prolactin level of 3000 plus.	
	Radiololgy			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.

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

Report Ospitalisat Onset D Outco	ate: me: Unknown	Seq:	1		Gender: M Weight: Age: DOB: Causality: Causality possible		
action D	etai ferred Term	Seve	erity	Repor	Description	Treatment	
Speech diso			,		,		
<i>f</i> ledicine	Dotails:						
ENDEP (Other				Reas	on:		
.		0.0					
3atch TEMAZEPAN	n: // (Other drug)	3ta	rted:	Reas	Stopped:		
	(0.0				
3atch		3ta	rted:		Stopped:		
ZOLOFT (Sus	spected)		0.0	Reas	on:		
3atch	1:	3ta	0.0 rted:		Stopped:		
	<u>y Investigati</u>		B. F 1				
Date	Туре	Range	Date Tested	Result		Details	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

 Spitalisation:
 Age: 36

 Onset Date: 05/07/2001
 DOB: 21/09/1964

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

10404011 20441		-	-
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

3atch: 3tarted: 02/07/2001 3topped: 07/07/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Reactions would appear overnight and recede by day.



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

Rep	ort	Detail
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Case Number:166452Seq:1Gender:UReported:16/07/2001Weight:69.00Hospitalisation:Admitted to hospitalAge:35

Onset Date: 28/06/2001 DOB: 11/10/1965

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Tremor		Shaky legs.	
Paraesthesia		Tingling left arm and side of face.	
Dysarthria		Unable to speek properly.	
Thinking abnormal		Vocing thought.	
Asthenia			
Hot flush			Zoloft ceased. admitted to hospital. still recovering
Nausea			77777777
Somnolence			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 26/06/2001 3topped: 30/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal	saotion Botal						
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				
Thinking abnormal		Thought disorder					
Delusion							
Paranoia							
Psychotic disorder							

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 21/12/1999 3topped: 30/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 13/7/01.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Cuotion Detai						
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 childhod

 Tablet
 50.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 06/07/2001
 3topped: 13/07/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking ritalin.



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

oport Dotoil					
eport Detail Case Number: 166841 Reported: 25/07/200 espitalisation: Onset Date: 25/06/200 Outcome: Recovere)1		Gender: M Weight: Age: 40Y DOB: Causality: Causality possible		
action Detai Preferred Term	Severity	Report Des	ecription	Treatment	
ggression		Had hit mother.	SCIPTION	Zoloft was ceased.	
edicine Details:		Reason:	Depression		
Tablet	0.0		Ora	al	
Batch:	Started:	S TERM	Stopped:	1W	
METHADONE HYDROCHLORII		Reason:	торрош.		
	0.0)			
3atch:	Started:		Stopped:		
aboratory Investigat	ions:				
aboratory Investigat	t ions: Range Date Te	ested Result		Details	
aboratory Investigat Date Type		ested Result		Details	



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

 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 Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			
Hyponatraemia			Patient wqas hospitalised. date of recovery 27.7.01.

Medicine Details:

OMEPRAZOLE (Other drug)			Reason:	Peptic ulcer nos w/o ment perf
	20.0	Milligram	Daily	
3atch:	Started:			Stopped:
IRBESARTAN (Other drug)			Reason:	Essential benign hypertension
	150.0	Milligram	Daily	
3atch:	Started:			Stopped:
TEMAZEPAM (Other drug)			Reason:	
TEMAZEPAM (Other drug)	10.0	Milligram	Reason: Daily	
TEMAZEPAM (Other drug) 3atch:	10.0 Started:	Milligram		Stopped:
, ,	Started:	Milligram		Stopped: Diabetes mellitus
3atch:	Started: Irug)	Milligram Milligram	Daily	• • • • • • • • • • • • • • • • • • • •

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



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

Report Detail									
Case Number:	30/07/2001 Admitted to hospi 22/07/2001 Recovered	Seq: tal	1					60.00	
	ails: ROCHLORIDE (Susp			Milligram	Reason:	Depression			
3atch:		3tar	ted:			Stopped	: 21/07/2001	<u> </u>	
Laboratory In	vestigations:								
Additional Inf	ormation:								

Report Run 27/07/200 03:31PN Database: pusime ADRS004 Page 513 of 591



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			
Nausea			Required a visit to doctor. date of recovery 30.3.01 zyban

Medicine Details:

Micalcinic Details.		
ZYBAN SR (Interaction)	Reason:	
	0.0	
3atch:	Started: 20/02/2001 Stopped:	
ZOLOFT (Interaction)	Reason: Depression	
	200.0 Milligram Daily	
3atch:	Started: 01/09/1999 Stopped:	
TRIFEME 28 (Other drug)	Reason: Contraception	
	1.0 Dose Unspecified Daily	
3atch:	Started: Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Syncope			Treated with rythmodan.
Tachycardia			

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason:	Myxedema	
Tablet	0.0			Oral
3atch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	Depression	
Tablet	200.0 Milligram	Daily	,	Oral
Зatch:	Started: 01/01/2000		Stopped:	

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Caction Betai	dotton Betai							
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 Mil	1illigram Daily	Oral
	3atch:	Started:		Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			Zoloft ceased.

Medicine Details:

ZOLOFT (Interaction)			Reason:	Depression	
Tablet	50.0	Milligram	Daily		Oral
3atch:	Started: 18	8/07/2001		Stopped:	26/07/2001
PHENOBARBITONE (Interaction)			Reason:	Other&unspec	cified epilepsy
Tablet	120.0	Milligram	Daily		Oral
3atch:	Started:		L TERM	Stopped:	
EPILIM (Interaction)			Reason:	Other&unspec	cified epilepsy
Tablet	2.0) Gram	Daily		Oral
3atch:	Started:		L TERM	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Epilepsy since age 11, fit free for 15 years.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Developed buccal lingual movements.	

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 0.0
 Oral

 3atch:
 3tarted:
 01/12/1990
 3topped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

teaction Detai			
Preferred Term	Severity	Report Description	Treatment
Apathy			Zoloft ceased suddenly of patient's own accord.

Medicine Details:

 ZOLOFT (Suspected)
 Reason:
 Depression

 Tablet
 200.0 Milligram
 Daily
 Oral

 3atch:
 Started:
 Stopped:
 01/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

The dose stop date is not accurate but indicates the drug was stopped sometime around june.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 27/06/2001

Age: 11Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detail

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Choreoathetosis		Chorea like movements.	
Speech disorder		Developed mutism areoun the 27.6.01.	
Agitation			Patient was hospitalised.
Dystonia			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

Tablet 50.0 Milligram Daily Oral

Заtch: **Зtarted**: 01/05/2001 **Зtopped**: 30/06/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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	Gen	der: F
Reported: 08/08/2001		Wei	ght: 93.00
Hospitalisation:		A	.ge : 56
Onset Date: 03/08/2001		D	OB : 02/09/1944
Outcome: Recovered		Causa	lity: Causality probable
Reaction Detai			
Preferred Term	Severity	Report Description	Treatment
Haematuria			Patient required a visit to a doctor; medications ceased.
Rectal haemorrhage			
r cota nacmonnage	1		

Medicine Details:

LIPITOR (Other drug)	Reason:				
	0.0				
Зatch:	Started:	L TERM	Stopped:		
DICHLOTRIDE (Other drug)		Reason:			
	0.0				
3atch:	Started:	L TERM	Stopped:		
PREMARIN (Other drug)		Reason:			
	0.0				
Зatch:	Started:	L TERM	Stopped:		
TAGAMET (Other drug)	Reason				
	0.0				
3atch:	Started:	L TERM	Stopped:		

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered on the 6/8/2001.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

Case Number:	167296	Seq: 1		Gender:	F
Reported:	08/08/2001			Weight:	93.00
Hospitalisation:				Age:	
Onset Date:	03/08/2001				02/09/1944
Outcome:	Recovered		(Causality:	Causality probable
Reaction Detai	i				
Madiaina Dat	aila.				
Medicine Det ZOLOFT (Suspect			Reason: Depression		
Tablet	. cu j	25.0 Milligram	Daily	Oral	
3atch:		Started: 02/08/2001	Stopped:		
	41. 41				
Laboratory In	nvestigations:	1			
Additional In					
Patient recovered	on the 6/8/2001.				
aport Pup 27/07/200	0 03:31DN Data	abasa: nusima	ADB\$004		Daga 500 of 501



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

 3atch:
 Started:
 Stopped:

Laboratory Investigations:

Date	Туре	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.



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

Report D)etail
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 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 Detai

todotion bottan			-
Preferred Term	Severity	Report Description	Treatment
Weight increased			Diet control and excercise with no effect

Medicine Details:

Medicine Details.					
ZOLOFT (Suspected)		Reason:	Depression		
	100.0 Milligram	Daily			
3atch:	3tarted: 01/07/1999		Stopped:	CONTIN	
CENTRUM TABLETS (Suspected)		Reason:			
Tablet	1.0 Dose Uns	pecified Daily	Oral		
3atch:	Started:	L TERM	Stopped:	CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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:
 60.0

Reported: 13/08/2001 Weight: 60.00 Hospitalisation: Age: 17

Onset Date: DOB: 19/05/1984

Outcome: Recovered Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Wrist slashing	ricatilient
Agitation			Required a visit to doctor. ceased zoloft and changed to
Tremor			avanro

Medicine Details:

LEVLEN ED (Other drug) Reason: Contraception

1.0 Dose Unspecified Daily

3atch: Started: 20/11/2000 Stopped: CONTIN

ZOLOFT (Suspected) Reason: Depression

150.0 Milligram Daily

3atch: 3tarted: 09/10/2000 **3topped:** 15/03/2001

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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

 3atch:
 3tarted:
 15/11/2000
 3topped:
 28/01/2001

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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		G	ender: M	
Reported:		•				/eight:	
spitalisation:						Age: 17Y	
Onset Date:						DOB:	
Outcome:	Recovered				Cau	sality: Causality prob	oable
action Detai						,	
Preferre		Seve	erity	Report	Description	Treatmen	ıt
ggression				•	·	Zoloft ceased.	
edicine Deta			0.0	Reaso		rol	
Tablet 3atch:		240	0.0 rted:		Stopped:	ral 9M	
					Nobbea.	• • • • • • • • • • • • • • • • • • • •	
aboratory In	vestigation	ne:					
Date	Type	Range	Date Tested	Result		Details	
dditional Inf	ormation:						
ort Run 27/07/200	03:31PN [Database: pu	sime	A	DRS004	Page 527	of 591



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

Report D)etail
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Case Number: 167619 Seq: 1 Gender: M
Reported: 16/08/2001 Weight:
Hospitalisation: Age:
Onset Date: DOB:

Outcome: Unknown Causality: Causality possible

Reaction Detai

Preferred Term	Severity	Report Description	Treatment
Breast pain		Sore enlarged left breast.	

Medicine Details:

Medicine Details.			
PROTHIADEN (Other drug)	;	Reason:	
	0.0		
3atch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily Oral	
3atch:	Started: 01/02/2001	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report De	tail					
Report Hospitalisati					Wei	der: U ght: 55.00 Age: 32
	ate: 10/08/200					OB : 01/09/1968
Outco Reaction D	me: Not yet re	covered			Causa	lity: Causality possible
	ferred Term	Severi	tv	Repor	Description	Treatment
Diarrhoea	101104 101111	007011	.9	Пороп	Воссираси	riodanone
Dry mouth						
Headache						
Myalgia						
Nausea						Required a visit to doctor.
Vomiting						
Medicine ZOLOFT (Sus			25.0 Mill	Reas igram	on: Depression Daily	
3atch	:	Starte	d: 09/08/2			3/2001
Laborator	y Investigat	ions:				
Date	Type		ate Tested	Result		Details
		-				
Additiona	l Informatio	n:				



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

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: ℓ	Jnspecified anemia	
Tablet	0.0		Oral	
3atch:	Started:		Stopped:	
DEPO-PROVERA (Other drug)		Reason:	Contraception	
	0.0			
3atch:	3tarted: 08/01/2001		Stopped:	
TRIPRIM (Other drug)		Reason:	Othr diseases of urinary tract	
	0.0			
3atch:	Started: 08/06/2001		Stopped: 11/06/2001	
ZOLOFT (Suspected)		Reason:	Depression	
	50.0 Milligram	Daily		
3atch:			Stopped: 14/08/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal		_	
Preferred Term	Severity	Report Description	Treatment
Nausea		Ongoing nausea.	
Agitation			Zoloft continues and the events are still present.

Medicine Details:

ZOLOFT (Suspected) Reason:
Tablet 50.0 Milligram Daily Oral

3atch: 3tarted: 01/01/2000 **3topped:**

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100000000000000000000000000000000000000	-	-	
Preferred Term	Severity	Report Description	Treatment
Aggression			
Agitation			Zoloft ceased.

Medicine Details:

ZOLOFT (Suspected)

Tablet

100.0 Milligram

Daily

Oral

Started: 01/11/2000

Stopped:

Laboratory Investigations:

Date	Туре	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.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal			
Preferred Term	Severity	Report Description	Treatment
Suicide attempt			Patient was hospitalised. patient was released with

Medicine Details:

<u>Medicine Details:</u>			
ALCOHOL (Suspected)		Reason:	
	0.0		
Зatch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	150.0 Milligram	Daily Oral	
3atch:	Started: 01/10/2000	Stopped:	

Laboratory Investigations:

Date	Туре	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.



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

 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 Detai

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia		Suspected SIADH	Zoloft ceased.

Medicine Details:

Modifile Botalie.			
DIGOXIN (Other drug)		Reason:	
Tablet	0.0		Oral
3atch:	Started:	Stopped:	
ALLOPURINOL (Other drug)		Reason:	
Tablet	0.0		Oral
3atch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
3atch:	Started: 01/07/2001	Stopped:	28/07/2001

Laboratory Investigations:

Date	Туре	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 somtime in the month. diagnosed with subacute bacterial endocarditis.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Reported: 23/08/200 ospitalisation:	Seq: 1		Gender: M Weight: Age:			
Onset Date:			DOB:			
Outcome: Not yet re	covered:		Car	usality: Causality probable		
eaction Detai						
Preferred Term	Severity	Repo	rt Description	Treatment		
gitation				Zoloft ceased.		
ledicine Details: ZOLOFT (Suspected)		Reas				
Tablet		Milligram	•	Dral		
3atch:	Started:		Stopped:	4D		
aboratory Investigat	tions:					
Date Type	Range Date Tes	sted Result		Details		
Additional Informatio	n:					
oort Run 27/07/200 03:31PM	Database: pusime		ADRS004	Page 535 of 591		



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

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 Detai

Preferred Term	Severity	Report Description	Treatment
Convulsion			Zoloft ceased.

Medicine Details:

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

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

teaction Detai	_		
Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Paraesthesia fingers.	
Conjunctival haemorrhage		Sub-conjunctival haemorrhage r eye 2 days	
Headache			Required a visit to doctor.
Photophobia			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 07/07/2001 3topped: 19/08/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 27/8/01.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea		Bilateral galactorrhoea	Required a visit to doctor.

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

125.0 Milligram Daily

3atch: **3tarted**: 01/01/1998 **3topped**: CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 27/08/2001
Age: 37Y
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

<u> </u>				
Preferred Term	Severity	Report Description	Treatment	
Urticaria		Itchy rash all over body	Patient was admitted to	
Arthralgia			1 11 . 1	
Myalgia				

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

Tablet 100.0 Milligram Daily Oral

 Заtch:
 Started:
 01/04/2001
 Эторред:
 CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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		Gen	der: F			
Reported: 07/09/2001	•	Weight: 70.00					
Hospitalisation:		Age : 81Y					
Onset Date: 22/08/2001		DOB:					
Outcome: Recovered			Causa	lity: Causality probable			
Reaction Detai							
Preferred Term	Severity	Report	Description	Treatment			
Confusional state							
Delirium							
Medicine Details: SERTRALINE HYDROCHLORIDE (Suspected) Tablet 25.0 Milligram Daily Oral 3atch: 3tarted: 17/08/2001 3topped: 03/09/2001							
Laboratory Investigation	ns:						
Date Type	Range Date Tes	ted Result		Details			
Additional Information:							



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 13/08/2001
DOB:

Outcome: Recovered Causality: Causality possible

Reaction Detai

104011011 20141			
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Patient was admitted to hospital; zoloft was ceased.

Medicine Details:

TAMOXIFEN CITRATE (Other drug)		Reason:	Malignant neo	plasm of breast
Tablet	20.0 Milligram	Daily		Oral
3atch:	Started:		Stopped:	
ZOLOFT (Suspected)		Reason:	Depression	
ZOLOFT (Suspected) Tablet	50.0 Milligram	Reason: Daily	Depression	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium		14/08/2001	129	

Additional Information:

Patient felt poorly before starting zoloft. patient had a parathyoidectomy and removal of cancer of the right breast by lumpectomy. physician felt patient was dehydrated so instructed_patient to increase fluid intake to start zoloft.

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

Report Detail	Re	ро	rt C	Deta	il
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Case Number:168246Seq: 1Gender: FReported:07/09/2001Weight:Hospitalisation:Admitted to hospitalAge: 37Y

Onset Date: 26/08/2001 DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion botal			
Preferred Term	Severity	Report Description	Treatment
Urticaria		Generalised urticarial rash all over	Patient was admitted to hospital; zoloft 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
3atch:	Started:		3topped:	27/08/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104011011 20141			=.
Preferred Term	Severity	Report Description	Treatment
Gynaecomastia			Patient required to visit a doctor; zoloft is withdrawn.

Medicine Details:

3atch:

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

Stopped:

3tarted: 17/04/2001

Laboratory Investigations:									
Date	Туре	Range	Date Tested	Result	Details				

Additional Information:

Patient was commenced on 25mg zoloft daily and increased to 50mg per day on the 1 may 2001.



Case Numb						
	ber: 168271	Seq:	1			Gender: F
-	ted: 10/09/200)1				Weight: 59.00
ospitalisati						Age : 56
	ate: 08/08/200				_	DOB: 05/10/1944
	me: Recovered	d			C	ausality: Causality probable
action D	etaı ferred Term	Seve	rity	Penor	Description	Treatment
ace oedem		Sevel			·	
race oedem Pruritus	ıa		Facia	ıl angioedema	1	Required a visit to doctor.
	Details:	(Other drug)		Reaso	on:	
	DROCHLORIDE (Other drug)	0.0	Rease	on:	Oral
THIAMINE HY	YDROCHLORIDE (et	(Other drug) Start		Reaso	on: Stopped:	Oral
Table 3atch	YDROCHLORIDE (et	Start		₹easc	Stopped:	Oral
THIAMINE HY Table 3atch	YDROCHLORIDE (et i:	Start			Stopped:	Oral
THIAMINE HY Table 3atch TISSUE SALT	YDROCHLORIDE (et i: TS M11/5X (Other of) i:	Start	0.0		Stopped:	Oral
THIAMINE HY Table 3atch TISSUE SALT	YDROCHLORIDE (et i: TS M11/5X (Other of) i:	Start drug)	0.0 ted:		Stopped: on: Stopped:	Oral
THIAMINE HY Table 3atch TISSUE SALT 3atch	rDROCHLORIDE (et i: IS M11/5X (Other of i: Other drug)	Start drug) Start	0.0 ted:	Reaso	Stopped: on: Stopped:	Oral
THIAMINE HY Table 3atch TISSUE SALT 3atch SPIRULINA (6	rDROCHLORIDE (et i: IS M11/5X (Other of i: Other drug)	Start drug)	0.0 ted:	₹ease	Stopped: Stopped: Stopped: Stopped:	Oral
THIAMINE HY Table 3atch TISSUE SALT 3atch SPIRULINA (6	rDROCHLORIDE (et i: IS M11/5X (Other of i: Other drug)	Start drug) Start	0.0 ted: 0.0 ted:	Reaso	Stopped: Stopped: Stopped: Stopped:	Oral
THIAMINE HY Table 3atch TISSUE SALT 3atch SPIRULINA (6 3atch	TOROCHLORIDE (et i: TS M11/5X (Other of i: Other drug) i: ACID (Other drug)	Start drug) Start Start	0.0 ted: 0.0 ted: 0.0	₹ease	Stopped: Stopped: Stopped: Stopped: Stopped:	Oral
THIAMINE HY Table 3atch TISSUE SALT 3atch SPIRULINA (6 3atch ASCORBIC A	CDROCHLORIDE (et i: IS M11/5X (Other of i: Other drug) i: ACID (Other drug)	Start drug) Start Start	0.0 ted: 0.0 ted: 0.0	₹ease	Stopped: Stopped: Stopped: Stopped:	Oral
THIAMINE HY Table 3atch TISSUE SALT 3atch SPIRULINA (6 3atch ASCORBIC A	TOROCHLORIDE (et i: TS M11/5X (Other of i: Other drug) i: ACID (Other drug)	Start Start Start	0.0 ted: 0.0 ted: 0.0	₹ease	Stopped: Stopped: Stopped: Stopped: Stopped:	Oral



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Case Number: 16	8271 S	ieq: 1		Gender:	F
Reported: 10	/09/2001			Weight:	59.00
lospitalisation:				Age:	56
Onset Date: 08	/08/2001			DOB:	05/10/1944
Outcome: Re	ecovered		С	ausality:	Causality probable
eaction Detai					
Madialna Datalli					
Medicine Details ZOLOFT (Suspected)	>.		Reason: Depression		
Tablet		50.0 Milligram	1 time	Oral	
Satch:		30.0 Milligram 3tarted: 08/08/2001		Olai	
satcn:		Started: 08/08/2001	Stopped:		
aboratory Inve	etigations:				
aboratory inve	sugations.				
Additional Infor					
Patient recovered 11/8	3/01.				



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion botal		-	
Preferred Term	Severity	Report Description	Treatment
Aggression		Extremely aggressive.	Tramadol ceased.
Paranoia		Rude with paranoid behaviour.	

Medicine Details:

TRAMADOL HYDROCHLORIDE (Interacti	on)	Reason: Pain	
Capsule	50.0 Milligram	As necessary	Oral
3atch:	Started: 19/07/2001	Stopped:	22/07/2001
ZOLOFT (Interaction)		Reason:	
	50.0 Milligram	Daily	
3atch:	3tarted: 12/07/2001	Stopped:	
PANADOL (Other drug)		Reason:	
PANADOL (Other drug)	2.0 Dose Unspe	Reason:	
PANADOL (Other drug) 3atch:	2.0 Dose Unspe Started: 12/07/2001		
, ζ,	•	cified As necessary	
Batch:	3tarted: 12/07/2001	cified As necessary 3topped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient also taking norvasc which was added and withheld over several weeks. history: hypercholesterol, hypertension, asthma/bronchitits, depressive illness, arthritis, seasonal hayfever, back problems, knee problems (both).

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Medicine Details:

MAXOLON (Other drug)	Reason:				
	10.0 Milligram	As necessary			
Зatch:	Started: 12/07/2001	Stopped:			
TEMAZEPAM (Other drug)	Rea	ason:			
	10.0 Milligram	As necessary			
Зatch:	Started: 20/07/2001	Stopped:			
	Reason:				
VENTOLIN (Other drug)	Rea	ason:			
VENTOLIN (Other drug) Inhalation	Rea 2.0 Dose Unspecified				
, ,					
Inhalation	2.0 Dose Unspecified Started: 12/07/2001	d As necessary Inhalation			
Inhalation 3atch:	2.0 Dose Unspecified Started: 12/07/2001	d As necessary Inhalation Stopped:			

Laboratory Investigations:

Additional Information:

Patient also taking norvasc which was added and withheld over several weeks. history: hypercholesterol, hypertension, asthma/bronchitits, depressive illness, arthritis, seasonal hayfever, back problems, knee problems (both).

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Medicine Details:

ATORVASTATIN (Other drug)	Reason:				
	20.0 Milligram	Daily			
Зatch:	Started: 12/07/2001	Stopped	:		
PREMARIN (Other drug)	Rea	son:			
	625.0 Microgram	Daily			
Зatch:	Started: 12/07/2001	Stopped	:		
BECOTIDE (Other drug)	₹ea	son:			
Inhalation	4.0 Dose Unspecified	l Daily	Inhalation		
Зatch:	Started: 12/07/2001	Stopped	:		
CLEXANE (Other drug)	₹ea	son:			
Injection	40.0 Milligram	Daily	Subcutaneous		
Зatch:	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/bronchitits, depressive illness, arthritis, seasonal hayfever, back problems, knee problems (both).

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Report De	tail					
Case Numb	er: 168478	Seq: 1			Gend	er: F
Report	ed: 18/09/2001	•			Weig	ht: 57.00
lospitalisati	on:				A	ge: 40
Onset Da	ate: 21/06/2001				DC	DB : 15/06/1961
Outcor	ne: Recovered				Causal	ity: Causality possible
eaction De	etai					
Pref	erred Term	Severity	Repor	t Description		Treatment
Muscle twitch	ning		Eye flickering.			
Anxiety						Date of recovery 10/07/2001.
Dry mouth						
Headache						
Insomnia						
Nervousness	}					
Tremor						
Medicine I	Details: MPLANT (Suspected)		Reas	on:		
		0.0)			
3atch:		Started: 2	8/05/2001	Stopped	d:	
ZYBAN SR (S			Reas			
Tablet			Dose Unspecified		Oral	
3atch:		Started:		Stopped		
ZOLOFT (Sus	pectea)	100 (Reas O Milligram	on: Depression Daily	n	
3atch:	:	Started:	, willigram	Stopped	d:	
1	y Investigations			1		2-4-4-
Date	Type F	Range Date Te	ested Result			Details
			L	<u> </u>		
Additional	Information:					



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

Report	Detail
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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 Detai

Veaction Detai			
Preferred Term	Severity	Report Description	Treatment
Urticaria		Extensive rash over trunk and abdomen.	
Vomiting			Required a visit to doctor.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)

Tablet 25.0 Milligram Daily Oral

3atch: Started: Stopped:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 168594 Reported: 24/09/2009 Iospitalisation: Onset Date: Outcome: Recovered		Gender: F Weight: Age: DOB: Causality: Causality possible					
eaction Detai			Caacamy, Caacamy possible				
Preferred Term	Severity	Re	port Description	Treatment			
Thrombocytopenia				Zoloft was ceased.			
Medicine Details: ZOLOFT (Suspected)		;	Reason: Depression				
Tablet	í	0.0	·	Oral			
3atch:	Started:		Stopped:				
_aboratory Investigati		Tested Result		Details			
Additional Informatior	1:						
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Bilat dorum feet.	Already and inpatient at

Medicine Details:

CEFTRIAXONE (Suspected)			₹eason:	Other cellulitis	and abscess
Injection		1.0 Gram	Daily		Intravenous
3atch:	Started:	11/09/2001		Stopped:	
FLAGYL (Suspected)			Reason:	Other cellulitis	and abscess
Tablet		1.2 Gram	Daily		Oral
3atch:	Started:	11/09/2001		Stopped:	20/09/2001
VANCOMYCIN HYDROCHLORIDE (Suspe	cted)		Reason:	Other cellulitis	and abscess
VANCOMYCIN HYDROCHLORIDE (Suspection Capsule	cted)	1.0 Gram	Reason: Daily	Other cellulitis	and abscess Oral
, ,	cted) Started:	1.0 Gram 11/09/2001		Other cellulitis	
Capsule	,				
Capsule 3atch:	Started:		Daily	Stopped:	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Allergy to penicillin.



Report Detail						
Case Number: 168661 Reported: 24/09/2001 Hospitalisation: Onset Date: 19/09/2001 Outcome: Not yet recovered Reaction Detai	Seq:	1				56.00
Medicine Details:						
MAGMIN (Suspected)			Reas	on:		
Tablet			4.0 Dose Unspecified	Daily	Oral	
3atch:	Sta	rted:	17/09/2001		Stopped:	
PHOSPHATE-SANDOZ (Suspected)			Reas			
Tablet Batch:	2to	rtad.	4.0 Dose Unspecified 17/09/2001	Daily	Oral Stopped:	
Laboratory Investigations:						
Additional Information: Allergy to penicillin.						



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

100000000000000000000000000000000000000			
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

3atch: 3tarted: 3topped: 17/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient commenced zoloft 25mg on 7/9/2001 for six days. reactions occurred when increased to 50mg.



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

Report Do	etail
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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 Detai

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal			

Medicine Details:

LIPITOR (Other drug)		Reason:	
	0.0		
3atch:	Started:	Stopped:	
NOTEN (Other drug)		Reason:	
	12.5 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
WARFARIN SODIUM (Other drug)		Reason:	
	4.5 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
ZOLOFT (Suspected)		Reason:	
	50.0 Milligram	Daily	
3atch:	Started: 01/04/2001	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	ALT = SGPT				Alt - 272.
	AST = SGOT				Ast - 84.
	GGT = SGGT =				Ggt - 210.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Reported: 05/10/2001 Hospitalisation: Onset Date: 20/04/2001 Outcome: Recovered Reaction Detai	Seq: 1				
Medicine Details: OLANZAPINE (Suspected)		2.5 Milligram	Reason:	Unspecified psychosis	
3atch:	Started:	03/04/2001	Daily	Stopped:	CONTIN
Laboratory Investigations:					
Additional Information:					

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

Report Detail	Re	ро	rt C	Deta	il
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 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 Detai

todotion Botal			<u> - </u>
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

3atch: 3tarted: 01/01/1990 3topped:

ZOLOFT (Suspected) Reason: Depression

0.0

3atch: Started: 01/07/2001 **Stopped:** 13/08/2001

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
	Histology				Biopsied perivascular dermatitis c/w drug reaction.



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

Rep	ort	Detail
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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 Detai

104011011 20141			-
Preferred Term	Severity	Report Description	Treatment
Dyspnoea		Airways decompensation.	
Urticaria	Severe		Patient was hospitalised. date of recovery: 12/10/2001.

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 15/08/2001 3topped: 24/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



DOB: 10/05/1931

Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

Onset Date: 04/08/2001

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Withheld sertraline,

Medicine Details:

PANADOL (Other drug)		Reason:	
	0.0	As necessary	
3atch:	Started:	Stopped:	CONTIN
RANITIDINE (Other drug)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started:	Stopped:	CONTIN
LIPITOR (Other drug)		Reason:	
	10.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN
NORVASC (Other drug)		Reason: Essential benign hype	ertension
	5.0 Milligram	Daily	
3atch:	Started:	Stopped:	CONTIN

Laboratory Investigations:

	<u> </u>				
Date	Туре	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	



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

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	ed		(Causality:	Causality possible
Reaction Detai						
Medicine Deta	ails:					
CLOPIDOGREL (O	ther drug)		Reason:			
		75.0 Milligram	Daily			
3atch:		Started:		Stopped:		CONTIN
QUININE (Other dr	rug)		Reason:			
		300.0 Milligram	Daily			
3atch:		Started:		Stopped:		CONTIN
TEGRETOL (Susp	ected)		Reason:			
		300.0 Milligram	Daily			
3atch:		3tarted: 01/06/2001		Stopped:	08/08/2001	
ZOLOFT (Suspect	ed)		Reason:	Depression		
		25.0 Milligram	Daily			
3atch:		Started: 03/08/2001		3topped:	05/08/2001	
l =	4! 4!					
Laboratory In	ivestigations:					
Additional Inf	formation:					

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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
Onset Date: 01/10/2001
Age: 72Y
DOB:

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

			a
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
3atch:	Started:		Stopped:
ZOLOFT (Suspected)		Reason:	Depression
Tablet	50.0 Milligram	Daily	y Oral
Зatch:	3tarted: 01/09/2001		Stopped:

Laboratory Investigations:

Date	Туре	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 sta rted sometime in the month.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

ospitalisatio	er: 169244 ed: 19/10/2001	Seq:	I			We	nder: M eight:	
-							Age: 47	Υ
Onset Da							DOB:	
	ne: Recovered					Caus	ality: Ca	ausality possible
action De							+	
Prefe	erred Term	Seve	erity	Report	t Descri	ption		Treatment
epatitis								
yponatraem								
uicide attem	npt							
ledicine [Ootoile:							
OLOFT (Sus				Reaso	on: D	epression		
Tablet			1.3 Gra		1 time	Ora	I	
3atch:		3ta	rted:			Stopped:		
	OL (Suspected)			Reaso	on:	•••		
	pplication		30.0 Dos	e Unspecified	1 time	Ora	ı	
3atch:		3ta	rted:			Stopped:		
MERSYNDOL				Reaso	on:			
Tablet			20.0 Dos	e Unspecified		Ora	ı	
3atch:		3ta	rted:			Stopped:		
STILNOX (Sus				Reaso	on:			
Tablet			10.0 Dos	e Unspecified	1 time	Ora	ı	
		3ta	rted:			Stopped:		
3atch:								
3atch:								
	y Investigatio	ns:	Date Tested	Result			Details	



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

Report Detail

Case Number:169289Seq:1Gender:MReported:22/10/2001Weight:86.00Hospitalisation:Admitted to hospitalAge:23

Onset Date: DOB: 25/10/1977

Outcome: Recovered Causality: Causality probable

Reaction Detail

todotion Botai			
Preferred Term	Severity	Report Description	Treatment
Hypertonia		Teeth clenching.	
Hypertonia			
Palpitations			
Tremor			Required a visit to doctor, patient was hospitalised.
Yawning			COTECO ZOLOTI

Medicine Details:

BECONASE (Other drug) Reason: Chronic nasopharyngitis

4.0 Dose Unspecified Daily

3atch: Started: Stopped:

ZOLOFT (Suspected) Reason: Depression

100.0 Milligram Daily

3atch: 3tarted: 12/12/2000 3topped: 10/08/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 20/8/01.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number	: 169315	Seq:	1		Ger	ider: U			
	: 22/10/200	_			Weight:				
Hospitalisation	:					Age:			
Onset Date	•				DOB:				
Outcome	: Unknown				Causa	ality: Causality poss	ible		
Reaction Deta									
Preferr	ed Term	Seve	erity	Report	Description	Treatment			
Serotonin syndr	ome								
Medicine De				Reaso	on:				
Tablet					Oral				
3atch:		3ta	rted:	Oral Stopped:					
Laboratory I	nvostigat	ione:							
Date	Type	Range	Date Tested	Result		Details			
Additional Ir	formatio	n:							
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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem Mart Sertraline, Concorz, Eleva 100, Eleva 50, GenRx Sertraline, SERTRALINE HYDROCHLORIDE, Sertraline-DP 100, Terry White Chemists Sertraline, Xydep, ZOLOFT

Report Deta	ıil
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 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 Detai

	<u> </u>	-	
Preferred Term	Severity	Report Description	Treatment
Delusion			
Paranoia			Patient hospitalised. zoloft

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

 Tablet
 500.0 Milligram
 Daily
 Oral

 3atch:
 3tarted: 01/09/2001
 \$topped: 28/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Report Detail	Re	ро	rt C	Deta	il
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 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 Detai

todotion Dotal		_	
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

3atch: 3tarted: 14/05/1999 3topped: 21/05/1999

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Report Detail

THERAPEUTIC GOODS ADMINISTRATION **Public Case Detail**

Case Number: 169406 Reported: 22/10/2001 Hospitalisation: Onset Date: Outcome: Not yet rec			Gender: F Weight: Age: 18Y DOB: Causality: Causality possible				
leaction Detai							
Preferred Term	Severity	Report	Description	Treatment			
Affect lability Agitation							
Medicine Details: ZOLOFT (Suspected)		Reaso					
Tablet 3atch :	100.0 M Started:	lilligram	Daily Oral Stopped:	CONTIN			
Laboratory Investigati	ons:						
Date Type	Range Date Tester	d Result		Details			
Additional Information	:						
eport Run 27/07/200 03:32PN	Database: pusime	A	DRS004	Page 567 of 591			



Report Deta							
Case Number		Seq: 1				Gender:	M
Reported ospitalisation	: 22/10/2001 :					Weight: Age:	55Y
Onset Date						DOB:	301
	: Not yet reco	vered					Causality possible
eaction Deta	ai	<u>-</u>	<u>.</u>			<u>-</u>	
Preferr	red Term	Sever	ity	Repor	t Description		Treatment
Affect lability							
gitation							
ledicine De ZOLOFT (Suspe				Reas	on: Depression		
Tablet	,		100.0 Milli		Daily Oral		
3atch:		Starte	Started:		Stopped:		CONTIN
_aboratory I							
Date	Туре	Range [Date Tested	Result		Details	3
Additional Ir	nformation:						



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Dystonia			Required a visit to doctor. date of recovery 16.10.01.
Dysarthria			

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 3tarted: 15/10/2001 3topped: 16/10/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Also same effect with cipramil 20mg.



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Hospitalisation Onset Da	ed: 02/11/200 on: ite: 25/10/200 ne: Recovere)1	1				74.00
Reaction De	erred Term	Seve	erity	Repor	Description		Treatment
Coma				a for 20 min.	2 000	27/1	0/01 - date of recovery.
						requ	uired a visit to doctor.
Chest pain	_						
Hypoaesthes	ia						
Nausea Paraesthesia							
Vomiting							
Medicine I ZOLOFT (Sus			50.0 Milli		Daily		
3atch:		3taı	ted: 25/10/20	001	Stopped:	26/10/200	1
Laboratory Date	/ Investigat	i ons: Range	Date Tested	Result		Deta	iils
Date	туре	Range	Date Tested	rtesuit		Deta	
Additional	Informatio	n:					



Report De	etail							
Case Num	ber: 169690	Seq:	1			G	ender:	M
Repor	rted: 01/11/200)1				W	eight:	
ospitalisat	tion:						Age:	66Y
Onset D							DOB:	
	ome: Recovere	ed				Cau	sality:	Causality possible
eaction D	Detai eferred Term	Sev	ority.	Report	Door	printion	-	Treatment
Aggression	elerred reim	Sev	enty	Кероп	Desc	приоп	Zolo	oft ceased.
<u>Medicine</u> Aricept (O				Reaso	n:	Presenile dement	ia	
Table	et		10.0 Mill	igram	Daily	O	ral	
3atcl		3ta	rted:			Stopped:		
ZOLOFT (Su				Reaso		Depression		
Table 3atcl			50.0 Mill	igram	Daily	Oi Stopped:	ral	
aborato	ry Investigat	Range	Date Tested	Result			Deta	nile
Date	Турс	runge	Date Tested	resuit			Dett	ano .



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

Re	ро	rt	De	tail
Re	þυ	ΙL	De	lan

 Case Number:
 169701
 Seq: 1
 Gender:
 F

 Reported:
 02/11/2001
 Weight:
 51.0

Reported: 02/11/2001 Weight: 51.00 Hospitalisation: Age: 30

Onset Date: DOB: 05/08/1971

Outcome: Not yet recovered Causality: Causality possible

Reaction Detai

todotion Dotal		<u> -</u>	
Preferred Term	Severity	Report Description	Treatment
Asthenia		Absolute exhaustion.	
Fatigue		Extreme lethargy.	
Libido decreased			Required a visit to doctor for

Medicine Details:

Medicine Details.				
ZOLOFT (Suspected)			Reason:	Depression
	50.0	Milligram	Daily	
Зatch:	Started:			Stopped:
LITHIUM CARBONATE (Suspected)			Reason:	
	500.0	Milligram	Daily	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion Botal		<u> </u>	
Preferred Term	Severity	Report Description	Treatment
Confusional state	Required Visit to Doctor		Stopped vioxx 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)		Reas	on:	Osteoarthritis	
Oral application	2.0	Dose Unspecified	As ne	cessary	Oral
Зatch:	Started:			Stopped:	
XALATAN (Other drug)		Reas	on:	Unspecified gl	aucoma
Eye Drops	2.0	Dose Unspecified	Daily		Ophthalmic
3atch:	Started:	L TERM		Stopped:	
KEELEV (OU. I.)		Reas	oni	Otre non infont	Prorecit discosoo
KEFLEX (Other drug)		(eas	on.	Oli alios illieco	Sparasit diseases
Oral application	3.0		Daily	Otrailos imeca	Oral
, σ,				Stopped:	·
Oral application		Dose Unspecified	Daily		Oral
Oral application 3atch:	Started: 1	Dose Unspecified 5/08/2001	Daily	Stopped:	Oral

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient has infection and #(I)nof.



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

Report Detail						
	Seq: 1			(Gender: Weight: Age: DOB: Causality:	
Medicine Details:						
ZOLOFT (Suspected)			Reason:	Depression		
Tablet		50.0 Milligram	Daily		Oral	
3atch:	Started:	30/07/2001	3	Stopped:	08/08/2001	
ZOLOFT (Suspected) Tablet	10	00.0 Milligram	Reason:	Depression	Oral	
3atch:		08/08/2001	Daily	Stopped:	16/08/2001	
Saton.	- Juntou.	00/00/2001		лоррец.	10/00/2001	
Laboratory Investigations:						
Additional Information:						
Patient has infection and #(I)nof.						

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

Report	t Detail
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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 Detai

	1		
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

3atch: 3tarted: 26/09/2001 3topped: 29/09/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

todotion botal			
Preferred Term	Severity	Report Description	Treatment
Depression		Severe suicidal depression, life threatening	Date of recovery 12/06/01. zoloft ceased.
Suicide attempt			

Medicine Details:

ASMOL (Other drug)		Reason:	Asthma	
	0.0			
3atch:	Started:	L TERM	Stopped:	CONTIN
ATROVENT (Other drug)		Reason:	Asthma	
	0.0			
Batch:	Started:	L TERM	Stopped:	CONTIN
MONOPLUS 10/12.5 (Other drug)		₹eason:	Essential benign hy	pertension
	0.0			
Batch:	Started:		Stopped:	CONTIN
ALODORM (Other drug)	Reason:			
	10.0 N	Milligram Daily		
Batch:	Started:	L TERM	Stopped:	CONTIN

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Severe suicidal depression after taking first zoloft tablet 50mg. depression b egan within 12 hrs and continued unabated until zoloft was ceased 21 days late r. took approx 3 weeks to fully recover.

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

 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 Detai

Medicine Details:

MEGICINE DETAILS.							
WARFARIN SODIUM (Other drug)			Reason:				
	2.0	Milligram	Daily				
3atch:	Started:	L	. TERM	Stopped:			
ZOLOFT (Suspected)			Reason:				
Tablet	50.0	Milligram	Daily		Oral		
3atch:	Started:			Stopped:		21D	

Laboratory Investigations:

Additional Information:

Severe suicidal depression after taking first zoloft tablet 50mg. depression b egan within 12 hrs and continued unabated until zoloft was ceased 21 days late r. took approx 3 weeks to fully recover.

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Report Deta	nil						
- - - - - - - - - - - - - - - - - - -	d: 21/11/200 n:	Seq:	1			Gender: Weight: Age:	: : A5
Onset Date	e: Recovere	d			(DOB:	: Causality possible
eaction Det		·u			`	Jausanty.	Causanty possible
	red Term	Seve	rity	Report	Description		Treatment
Extrasystoles			Runs	of dropped b	eats.	Cea	ised zoloft.
Medicine De				Reaso	n: Depression		
Tablet	, , , ,		25.0 Milli		Daily	Oral	
3atch:		3tar	ted:		Mannadi		OD.
					Stopped:		8D
				Doguit	жоррец:	Date	
Laboratory Date	Investigat		Date Tested	Result	жоррец:	Deta	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

104011011 20141			=
Preferred Term	Severity	Report Description	Treatment
Hyponatraemia			Ceased sertraline and started on citalapram.

Medicine Details:

Medicine Details.							
IRBESARTAN (Other drug)	Reason:						
	150.0	Milligram	Daily	,			
Зatch:	Started:		L TERM	Stopped:		CONTIN	
ASPIRIN (Other drug)			Reason:				
	150.0	Milligram	Daily	1			
3atch:	Started:		L TERM	Stopped:		CONTIN	
SERTRALINE HYDROCHLORIDE (S	uspected)		Reason:	Depression			
	25.0	Milligram	Daily	1			
3atch:	Started: 01.	/09/2001		Stopped:	20/09/2001		

Laboratory Investigations:

Date	Туре	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.

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

Report D)etail
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 Case Number:
 170287
 Seq: 1
 Gender:
 F

 Reported:
 26/11/2001
 Weight:

Hospitalisation: Hospitalisation prolonged **Onset Date**: 11/08/2001 **ODB**:

Outcome: Recovered Causality: Causality possible

Reaction Detai

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		
Зatch:	Started:			Stopped:	CONTIN	
SIMVASTATIN (Other drug)			Reason:			
Tablet	10.0	Milligram	Daily	Oral		
Зatch:	Started:			Stopped:	CONTIN	
IRBESARTAN (Other drug)			Reason:			
IRBESARTAN (Other drug) Tablet	150.0	Milligram	Reason: Daily	Oral		
` "	150.0 Started:	Milligram		Oral	CONTIN	
Tablet		Milligram			CONTIN	
Tablet 3atch:	Started:	Milligram Milligram	Daily		CONTIN	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details
	Sodium				Sodium = 125



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

Reported: 26/11/2001 ospitalisation: Hospitalisation pro Onset Date: 11/08/2001	Seq: 1						
Reported: 26/11/2001 ospitalisation: Hospitalisation pro Onset Date: 11/08/2001	Seq: 1						
spitalisation: Hospitalisation pro Onset Date: 11/08/2001						Gender:	F
Onset Date: 11/08/2001						Weight:	
	longed					Age:	78Y
A. (DOB:	
Outcome: Recovered					•	Causality:	Causality possible
action Detai							
ledicine Details:							
/ERAPAMIL HYDROCHLORIDE (Other d	rug)			Reason:			
Tablet		80.0	Milligram	Da	nily	Oral	
Batch:	Started		J -		Stopped:		CONTIN
NDAPAMIDE HEMIHYDRATE (Suspected	d)			Reason:			
Tablet		2.5	Milligram	Da	nily	Oral	
3atch:	Started	:	L	TERM	Stopped:	10/08/2001	
SERTRALINE HYDROCHLORIDE (Suspe	cted)			Reason:	Depression		
Tablet		50.0	Milligram	Da	nily	Oral	
3atch:			/07/2001		Stopped:	04/08/2001	
AMITRIPTYLINE HYDROCHLORIDE (Sus	pected)			Reason:	Depression		
AMITTAL TILINE ITT DICOCITEORIDE (308	•	2.0	Dose Unsp			Oral	
Tablet							

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Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

teaction Detai		_	
Preferred Term	Severity	Report Description	Treatment
Chills			
Cognitive disorder			
Tremor			Zoloft ceased. given

Medicine Details:

ZOLOF1 (Suspected)		Reason:	Depression		
	0.0				
3atch:	Started: 01/12/2000		Stopped:	04/01/2001	
DOTHEP (Suspected)		Reason:	Depression		

Tablet 25.0 Milligram As necessary Oral **3atch: 3tarted:** 04/01/2001 **3topped:**

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



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

Report D)etail
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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 Detai

Cuction Detai			
Preferred Term	Severity	Report Description	Treatment
Electrocardiogram abnormal			
Tachycardia			Zoloft ceased. given aspirin

Medicine Details:

ZOLOFT (Suspected) Reason: Depression

0.0

3atch: **3tarted**: 01/12/2000 **3topped**: 04/01/2001

DOTHEP (Suspected) Reason: Depression

Tablet 25.0 Milligram As necessary Oral **3atch**: **3tarted**: 04/01/2001 **3topped**:

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details



Reported spitalisation Onset Date	: 27/12/200 : Recovered	00	1		C	DOB:	60.00 88Y
	ed Term	Seve	erity	Repor	Description		Treatment
lushing				all over.	•		
hest pain						Stor	pped zoloft.
yspepsia							
edicine De							
STEMETIL (Other	r drug)			Reas	on:		
Tablet			0.0		As necessary	Oral	
Tablet 3atch:		3ta	0.0		Stopped:	Oral	
Tablet 3atch: TEMAZEPAM (Ot		€ta	rted:	Reas	Stopped:		
Tablet 3atch: TEMAZEPAM (Ot Oral appli			rted: 10.0 Milli		Stopped: on: As necessary	Oral	
Tablet 3atch: TEMAZEPAM (Ot Oral appli 3atch:	ication	Sta	rted:	gram	Stopped: As necessary Stopped:		
Tablet 3atch: TEMAZEPAM (Ot Oral appli 3atch:	ication	Sta	rted: 10.0 Milli rted:	igram Reas	Stopped: on: As necessary Stopped: on:	Oral	
Tablet 3atch: TEMAZEPAM (Ot Oral appli 3atch: PANADEINE FOR	ication	Sta ug)	rted: 10.0 Milli rted:	gram	Stopped: on: As necessary Stopped: on:		
Tablet 3atch: TEMAZEPAM (Ot Oral appli 3atch: PANADEINE FOR	ication RTE (Other dru	Sta ug)	10.0 Millirted: 2.0 Dos	igram Reas	Stopped: As necessary Stopped: On: As necessary Stopped:	Oral	
Tablet 3atch: TEMAZEPAM (Ot Oral appli 3atch: PANADEINE FOR Tablet 3atch:	ication RTE (Other dru	Sta ug)	10.0 Millirted: 2.0 Dos	gram Rease se Unspecified Rease	Stopped: As necessary Stopped: On: As necessary Stopped:	Oral	
Tablet 3atch: TEMAZEPAM (Ot Oral appli 3atch: PANADEINE FOR Tablet 3atch: ZOLOFT (Suspec	ication RTE (Other dru	Sta ug) Sta	rted: 10.0 Milli rted: 2.0 Dos rted:	Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Re	Stopped: As necessary Stopped: As necessary Stopped: On: As necessary Stopped:	Oral	0
Tablet 3atch: TEMAZEPAM (Ot Oral appli 3atch: PANADEINE FOR Tablet 3atch: ZOLOFT (Suspect Tablet 3atch:	ication RTE (Other dru	Sta ug) Sta Sta	10.0 Milli rted: 2.0 Dos rted: 50.0 Milli	Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Re	Stopped: As necessary Stopped: As necessary Stopped: 1 time	Oral Oral	0
Tablet 3atch: TEMAZEPAM (Ot Oral appli 3atch: PANADEINE FOR Tablet 3atch: ZOLOFT (Suspect	ication RTE (Other dru	Sta ug) Sta Sta	10.0 Milli rted: 2.0 Dos rted: 50.0 Milli	Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Reason Re	Stopped: As necessary Stopped: As necessary Stopped: 1 time	Oral Oral	



Report Detail								
Case Number: 170632	Seq:	1			Gender: U			
Reported: 03/12/2001				Weight:				
spitalisation:					Age:			
Onset Date:					DOB:			
Outcome: Recovered				C	ausality: Ca	ausality poss	ible	
action Detai		.,		(D	<u> </u>	- , ,		
Preferred Term	Seve			Description		Treatment		
uicide attempt		Over	dosed on zolo	oft.				
edicine Details:								
OLOFT (Suspected)			Reas	on: Depression				
Tablet		0.0			Oral			
3atch:	€tart	ed:		3topped:				
aboratory Investigatio	ne:							
Date Type		Date Tested	Result		Details			
Турс Турс	range	Date residu	resuit		Details			
dditional Information:								
rt Dun 27/07/200 02:2004	Database: ::-:	mol	Λ.	DRS004		De-:- 505	of F04	
rt Run 27/07/200 03:32PN	Database: pusi	me ₁	А	レベシ004		Page 585	ot 591	



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Skin exfoliation			Ceased zoloft, treated with emollient creams.

Medicine Details:

MOXACIN (Other drug) Reason: Otr&nos infec¶sit diseases

1.5 Gram Daily

3atch: 31/07/2001 Stopped:

ZOLOFT (Suspected) Reason: Depression

50.0 Milligram Daily

3atch: 31/07/2001 Stopped: 20/08/2001

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

Patient recovered 28/8/01.



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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 Detai

Preferred Term	Severity	Report Description	Treatment
Dizziness Drug withdrawal syndrome		1 7	Sertraline ceased over one week, slowly, still had symptoms for 2 weeks later took single 50 mg tab sertraline resolved.
,			
Nervousness			
Paraesthesia			

Medicine Details:

Medicine Details.							
CHLORPROMAZINE HYDROCHLORIDE (C	ther drug)	Reason:					
	25.0	Milligram	D	aily			
Зatch:	Started:		L TERM		Stopped:		
SODIUM VALPROATE (Other drug)			Reason:	:			
	1.0	Gram	D	aily			
Зatch:	Started:		L TERM		Stopped:		
SERTRALINE HYDROCHLORIDE (Suspect	ted)		Reason:	:	Depression		
	50.0	Milligram	D	aily			
Зatch:	Started: 01	/07/2001			Stopped:	13/11/2001	

Laboratory Investigations:

Date	Туре	Range	Date Tested	Result	Details

Additional Information:

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



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

Report Detail	Re	po	rt C	Detail
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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 Detai

todotion Botai			
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)		Reas	on:	
	3.0	Milligram	Daily	
3atch:	Started:			Stopped:
ZOLOFT (Interaction)		Reas	on:	
	100.0	Milligram	Daily	
Заtch:	Started:			Stopped:
LANOXIN PG (Other drug)		Reas	on:	
	2.0	Dose Unspecified	Daily	
3atch:	Started:			Stopped:
EPILIM (Other drug)		Reas	on:	
EPILIM (Other drug)	1.0	Reas Gram	on: Daily	

Laboratory Investigations:

					
Date	Туре	Range	Date Tested	Result	Details
	International		10/12/2001	>10	



Report Detail

Case Number: 171015

Seq: 1

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Gender: M

Reported:					Weight:	
	Admitted to hospital				Age:	
Onset Date:						18/09/1920
Outcome:					Causality:	Causality possible
Reaction Detai						
Medicine Deta	ails:					
TEMAZE (Other dr				Reason:		
		10.0	Milligram	Daily		
3atch:		Started:			Stopped:	
EXELON (Other dr	ug)			Reason:		
		3.0	Milligram	Daily		
3atch:		Started:			Stopped:	
DITROPAN (Other	drug)			Reason:		
		10.0	Milligram	Daily		
3atch:		Started:			Stopped:	
Laboratory In	vestigations:					
Laboratory III	vestigations.					
Additional Inf	ormation:					



Date Range: 1 Jan 2000 To 31 Dec 2001 Unclear causality excluded GM medicines Only Tradenames: Chem 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

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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			
3atch:	Started: 01/01/1996		Stopped:	28/05/2001	
ZOLOFT (Suspected)		Reason:	Depression		
	150.0 Milligram	Daily			
3atch:	Started: 28/05/2001		Stopped:		CONTIN
TRAMAL (Suspected)		Reason:			
	100.0 Milligram	Daily			
3atch:	Started: 01/03/2001		Stopped:		CONTIN

Laboratory Investigations:

Date	Туре	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.

Report Run 27/07/200 03:32PN Database: pusime ADRS004 Page 590 of 591



Report Detail

THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

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

spitalisation: Onset Date:	: 03/12/2001 : : 03/04/2000 : Not yet reco					<pre>/eight: Age: DOB: sality: Causality possible</pre>
action Deta	-					
	ed Term	Sev	erity	Report D	escription	Treatment
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			0.0 arted:	Reason	: Stopped:	
SODIUM VALPRO 3atch:	OATE (Suspecte			Reason:	}topped:	
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3atch: AROPAX (Suspection Satch: ZOLOFT (Suspection)	DATE (Suspected) E (Suspected) cted)	Sta Sta Sta	0.0 arted: 0.0 arted: 0.0 arted:	₹eason ₹eason	Stopped: Stopped: Stopped:	Details

Additional Information:

Little boy was born 3/4/00. mother took sodium valproate from the time of conception until delivery at term. at 11 months old he had dysmorphic facial features (mild hypotelorism, epicanthic folds, infra-orbital ridging, upslanting palpable fissures, flat nasal bridge, anteverted nares, smooth philtrum, slightly thin upper lip) and metopic + right lamoidal craniosynosto- sis leading to trigonencephaly and asymmetrical brachycephaly. at this time his development was within the normal range.