



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181156
Reported: 07/01/2003

Seq: 1

Gender: F
Weight: 79.00

Hospitalisation:

Onset Date: 28/11/2002
Outcome: Recovered

Age: 41
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		Excessive sedation, slept for over 15 hours and then extremely drowsy	Patient already in hospital.

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started:	Stopped: 29/11/2002	
TRAMAL (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 29/11/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181191 **Seq:** 1 **Gender:** M
Reported: 08/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 15
Onset Date: 17/08/2002 **DOB:** 13/03/1987
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Blood creatine phosphokinase incr Malaise Myalgia Neuroleptic malignant syndrome		Fever, Malaise, Ck was elevated on 27/08/2002 at 402 but unnoticed until his admission in 04/11/2002 when Ck was 1963. Neuroleptic Malignant Syndrome. Myalgia.	Date hospitalised 04/11/02.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/11/2002	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason: Depression	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/11/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2003	Creatine	CK range	27/08/2002	402	
08/01/2003	Creatine	CK range	04/11/2002	1963	
08/01/2003	Creatine	CK range	06/11/2002	3553	

Additional Information:

The dose start and stop date for the drug Olanzapine - 01/02 and 10/02. Dose start date for Risperidone - 01/01 and dose start date for Sertraline - 01/02. Despite 10 days of treatment, patient remains psychotic.



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 181205 **Seq:** 1 **Gender:** F
Reported: 08/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 85
Onset Date: 10/09/2002 **DOB:** 27/10/1916
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pemphigoid		Bullous Pemphigoid. Severe rash and blisters all over body, started at the upper limb, then progressed to whole body and lower limbs.	Treated with Topical Eleuphrat to legs and arms, oral Prednisone, Azathioprine and Minomycin.
Dermatitis bullous	Severe		
Pemphigoid	Severe		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
Tablet	5.0 Milligram Daily Oral
Batch:	Started: 08/09/2002 Stopped: 10/09/2002 CONTIN

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2003	Histology				

Additional Information:

other drugs - Zocor, Prinivil, Normison and Panadol.



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 181218 **Seq:** 1 **Gender:** F
Reported: 08/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 31Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delusion		Delusions, Obsessive-Compulsive Disorder and Creatine Kinase Increased	
Blood creatine phosphokinase incr			
Obsessive-compulsive disorder			

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
Tablet	15.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/01/2003	Creatinine				

Additional Information:

Medical history - Drug and Alcohol problems.



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181336
Reported: 09/01/2003

Seq: 1

Gender: U

Weight: 60.00

Hospitalisation:

Onset Date: 30/10/2002

Age: 72

DOB: 03/10/1930

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance	Required Visit to Doctor	Suddenly unable or unwilling to walk 2 weeks into Zyprexa. Started walking 2 days after Zyprexa - no obvious neurological deficit	

Medicine Details:

NATRILIX (Other drug)		Reason:	
	1.0 Dose Unspecified Daily		
Batch:	Started:	L TERM	Stopped:
ZOLOFT (Other drug)		Reason:	
	100.0 Milligram Alternate days		
Batch:	Started:		Stopped:
ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram Daily	Oral	
Batch:	Started: 23/10/2002	Stopped:	19/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181475

Seq: 1

Gender: M

Reported: 13/01/2003

Weight: 0.00

Hospitalisation:

Onset Date: 20/11/2002

Age: 41

DOB: 13/12/1960

Outcome: Recovered

28/11/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal		Ataxia; slow movement, possible extrapyramidal syndrome.	

Medicine Details:

SOLIAN (Interaction)		Reason:	
	200.0 Milligram	Daily	
Batch:	Started: 04/11/2002	Stopped:	
ZYPREXA (Interaction)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 20/08/2002	Stopped:	
KALMA (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

patient was also taking Iron tablets.



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181587

Seq: 1

Gender: U

Reported: 14/01/2003

Weight: 0.00

Hospitalisation:

Onset Date: 06/12/2002

Age: 52

DOB: 02/07/1950

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Hyperglycaemia	

Medicine Details:

TOFRANIL (Other drug)		Reason:	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 04/12/2002	Stopped: 07/12/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2003	Biochemistry				

Additional Information:

Patient has Type 11 Diabetes monitors BSL, usually well controlled.



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 181640

Seq: 1

Gender: F

Reported: 15/01/2003

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date: 21/06/2002

DOB: 28/03/1959

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sleep walking	Required Visit to Doctor	Sleepwalking; and eating	Dose reduction from 20mg to 10mg.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 181691 **Seq:** 1 **Gender:** F
Reported: 15/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 45
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased	Caused or prolonged inpatient hospitalisation	Blood sugar increased	

Medicine Details:

ZYPREXA (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History - well controlled diabetes



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181694
Reported: 15/01/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 26/06/2002

Age: 78

DOB: 08/09/1923

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sepsis	Caused or prolonged inpatient hospitalisation	Septicaemia, Thrombocytopenia.	
Thrombocytopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GINSENG (Other drug)		Reason:	
Batch:	Started:	Stopped:	
MINIPRESS (Other drug)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History included osteomyelitis



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OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 181695 **Seq:** 1 **Gender:** M
Reported: 15/01/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 51
Onset Date: 29/10/2002 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation	Postural Hypotension - orthostatic hypotension	dose of olanzapine may be reduced to 2.5mg/day

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis
Tablet	5.0 Milligram Daily Oral
Batch:	Started: Stopped: 30/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of postural hypotension, anxiety, epilepsy



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181730
Reported: 16/01/2003

Seq: 1

Gender: F
Weight: 3.90
Age: 28D

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebral haemorrhage neonatal	Required Visit to Doctor	Acute haemorrhage in left basal ganglia of brain.	Phenobarbitone for seizures; ventilation; hyperbilirubinaemia requiring phototherapy
Infantile apnoeic attack		Apnoea and desaturation requiring ventilation for 1st p days of life.	
Congenital foot malformation		Baby dysmorphic - long, thin digits and overlapping 4th toes.	
Hyperbilirubinaemia		Conjugated hyperbilirubinaemia	
Weight decrease neonatal		Feed intolerance (weight dropped by 10% until day 20)	

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified psychosis
Tablet	Oral
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:
ZUCLOPENTHIXOL DECANOATE (Suspected)	Reason: Unspecified psychosis
Injection	Intramuscular
Batch:	Started: Stopped:
EPILIM (Suspected)	Reason:
Tablet	1.2 Gram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/01/2003	Electroencephalog				EEG - seizure from right temporal region.
16/01/2003	Other data				Acute haemorrhage determined by cerebral ultrasound and MRI scan

Additional Information:

Epilim 1200mg started in 1991 (first trimester of pregnancy), then 1500mg/day (at 20 weeks gestation age) and continues.
Clozaril, zyprexa and zuclopenthixol started in 1991.



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OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 181730
Reported: 16/01/2003

Seq: 1

Gender: F
Weight: 3.90
Age: 28D

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatosplenomegaly neonatal		Liver disturbances and hepato-splenomegaly.	
Convulsion		Seizures from day 8 onwards	
Hyperammonaemia		Transient hyperammonemia.	
Vomiting		Vomiting	
Hypoxia			

Medicine Details:

CLOZARIL (Suspected)	Reason: Unspecified psychosis
Tablet	Oral
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:
ZUCLOPENTHIXOL DECANOATE (Suspected)	Reason: Unspecified psychosis
Injection	Intramuscular
Batch:	Started: Stopped:
EPILIM (Suspected)	Reason:
Tablet	1.2 Gram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Epilim 1200mg started in 1991 (first trimester of pregnancy), then 1500mg/day (at 20 weeks gestation age) and continues.
Clozaril, zyprexa and zuclopenthixol started in 1991.



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 182677

Seq: 1

Gender: U

Reported: 11/02/2003

Weight: 42.00

Hospitalisation:

Age: 77

Onset Date: 31/10/2002

DOB: 21/09/1925

Outcome: Recovered

03/02/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		Parkinson's like change in tone with rigidity, cogwheel, tremor and shuffley gait.	
Parkinsonism		Parkinson's like change in tone with rigidity, cogwheel, tremor and shuffley gait.	
Tremor		Parkinson's like change in tone with rigidity, cogwheel, tremor and shuffley gait.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Paralysis agitans
Tablet	5.0 Milligram
	Daily
	Oral
Batch:	Started: 26/11/2001
	Stopped: 21/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 182708

Seq: 1

Gender: F

Reported: 11/02/2003

Weight: 82.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 07/07/1968

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal distension		Felt "bloated".	Olanzapine ceased.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 20/11/2002	Stopped: 03/01/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 182815 **Seq:** 1 **Gender:** F
Reported: 12/02/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 62
Onset Date: 20/01/2003 **DOB:** 21/09/1940
Outcome: Recovered 28/02/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Abnormal LFTs after commencement of olanzapine.	

Medicine Details:

FEXOFENADINE HYDROCHLORIDE (Other drug)		Reason: Chronic nasopharyngitis	
Oral application	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Oral application	5.0 Milligram	Daily	Oral
Batch:	Started: 10/01/2003	Stopped: 20/01/2003	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started: 17/01/2003	Stopped: 20/01/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/02/2003	ALT = SGPT				
12/02/2003	GGT = SGGT =				
12/02/2003	AST = ALP				

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 183825

Seq: 1

Gender: M

Reported: 07/03/2003

Weight: 0.00

Hospitalisation:

Age: 30Y

Onset Date: 30/05/2002

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose		Overdose and convulsions	
Grand mal convulsion			

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous treatment with Clozapine years ago from which he developed seizures. No family history of seizures.
Drug induced seizures.



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 183857

Seq: 1

Gender: U

Reported: 10/03/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date: 25/11/2002

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Glucose tolerance impaired		Glucose intolerance	

Medicine Details:

CLOZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 18/11/2002	Stopped:	Contin
OLANZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 09/10/2002	Stopped:	26/11/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 183966

Seq: 1

Gender: M

Reported: 06/02/2003

Weight: 0.00

Hospitalisation:

Onset Date: 22/11/2002

Age: 16Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Specialist Consultation	Mild neutropenia	

Medicine Details:

ZYPREXA (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 04/07/2002	Stopped: 22/11/2002	
EPILIM (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 27/07/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/02/2003	Neutrophils		15/10/2002	2.38	
06/02/2003	Neutrophils		22/11/2002	1.53	
06/02/2003	Neutrophils		27/12/2002	1.52	
06/02/2003	Neutrophils		06/12/2002	1.63	
06/02/2003	Neutrophils		15/01/2003	1.58	
06/02/2003	Neutrophils		12/12/2002	1.49	
06/02/2003	Neutrophils		02/12/2002	1.47	

Additional Information:

182488 is a duplicate



THERAPEUTIC GOODS ADMINISTRATION

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 183966

Seq: 1

Gender: M

Reported: 06/02/2003

Weight: 0.00

Hospitalisation:

Onset Date: 22/11/2002

Age: 16Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 04/07/2002	Stopped: 22/11/2002	
EPILIM (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 27/07/2002	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/02/2003	White blood cells		15/10/2002	4.5	
06/02/2003	White blood cells		22/11/2002	3.8	
06/02/2003	White blood cells		02/12/2002	3.8	
06/02/2003	White blood cells		06/12/2002	3.8	
06/02/2003	White blood cells		13/12/2002	3.6	
06/02/2003	White blood cells		27/12/2002	3.4	
06/02/2003	White blood cells		15/01/2003	3.6	

Additional Information:

182488 is a duplicate



THERAPEUTIC GOODS ADMINISTRATION

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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 184372

Seq: 1

Gender: F

Reported: 25/03/2003

Weight: 0.00

Hospitalisation:

Onset Date: 03/12/2002

Age: 89

DOB: 12/10/1913

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor	Required Visit to Doctor	parkinsonism type tremor in hands and arms (more noticable at rest).	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	7.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	25/12/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Increased Olanzapine from 5 mg to 7.5mg one month ago, tremor noticed since then,



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Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 184905 **Seq:** 1 **Gender:** M
Reported: 11/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22Y
Onset Date: 01/09/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Schizophrenia		Catatonic type schizophrenia,	Carbamazepine, Clonazepam 0.5mg daily and a reduction in the dose of Zyprexa to 7.5mg daily.
Convulsion		Convulsions generalized, tremulousness, hypotensive, myoclonus, sleep excessive, withdrawn, sluggishness, electroencephalogram abnormal, amnesia, confusion.	
Amnesia			
Confusional state			
Electroencephalogram abnormal			

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
10.0 Milligram	Daily Oral
Batch:	Started: 01/01/1996 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/04/2003	Electroencephalogram				
11/04/2003	Other data				

Additional Information:

At the age of one year he had status epilepticus and was treated with anticonvulsants for one year. He had a single seizure at age seven. History: Velo-cardio-facial syndrome (Digeorge's syndrome).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 184905 **Seq:** 1 **Gender:** M
Reported: 11/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22Y
Onset Date: 01/09/1999 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypersomnia			
Hypotension			
Myoclonus			
Sluggishness			
Social avoidant behaviour			
Tremor			

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
10.0 Milligram	Daily Oral
Batch:	Started: 01/01/1996 Stopped:

Laboratory Investigations:

Additional Information:

At the age of one year he had status epilepticus and was treated with anticonvulsants for one year. He had a single seizure at age seven. History: Velo-cardio-facial syndrome (Digeorge's syndrome).



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 184938 **Seq:** 1 **Gender:** M
Reported: 14/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 55
Onset Date: 02/09/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Neuro leptic malignant syndrome.	Gentle hydration iv, neuro obs, Nofree water ck levels and uec monitoring.
Altered state of consciousness	Life threatening		
Hyponatraemia	Life threatening		
Muscle rigidity	Life threatening		
Pneumonia aspiration	Life threatening		

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:		Stopped: 04/09/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/04/2003	Creatine		04/09/2002	151956	
14/04/2003	Other data				
14/04/2003	Sodium		04/09/2002	117	
14/04/2003	Urine osmolality		04/09/2002	251	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 184938 **Seq:** 1 **Gender:** M
Reported: 14/04/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 55
Onset Date: 02/09/2002 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis	Life threatening		

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 04/09/2002	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 185586

Seq: 1

Gender: F

Reported: 07/05/2003

Weight: 0.00

Hospitalisation:

Onset Date: 20/01/2003

Age: 72Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Normochromic normocytic anaemia		Normocytic anaemia, white blood cell count low	
Thrombocytopenia		Thrombocytopenia and lymphocyte count decreased.	
Lymphocyte count decreased			
White blood cell count decreased			

Medicine Details:

ATIVAN (Other drug)		Reason:	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
EFEXOR (Other drug)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/05/2003	Haemoglobin				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 185586

Seq: 1

Gender: F

Reported: 07/05/2003

Weight: 0.00

Hospitalisation:

Age: 72Y

Onset Date: 20/01/2003

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)

Reason: Schizophrenia

Tablet

225.0 Milligram

Daily

Oral

Batch:

Started: 05/02/2002

Stopped:

Contin

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 185614

Seq: 1

Gender: F

Reported: 07/05/2003

Weight: 100.00

Hospitalisation:

Age: 56

Onset Date: 08/04/2003

DOB: 31/07/1946

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Required Visit to Doctor	Urinary incontinence.	

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Zoloft, Marevan and Karvea.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 185798

Seq: 1

Gender: M

Reported: 12/05/2003

Weight: 0.00

Hospitalisation:

Age: 70Y

Onset Date: 15/04/2003

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced a seizure whilst driving his car and was involved in an accident.	

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: 15/04/2002 Stopped: Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186199
Reported: 26/05/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 99u

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Collapse, dramatic drop in platelets, diarrhoea, very low temperature	Rendered unconscious and needed respiratory assistance. Mirtazapine and Olanzapine ceased.
Body temperature decreased	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
MIRTAZAPINE (Suspected)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186199

Seq: 1

Gender: M

Reported: 26/05/2003

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
MIRTAZAPINE (Suspected)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186262

Seq: 1

Gender: F

Reported: 26/05/2003

Weight: 45.50

Hospitalisation:

Age: 82

Onset Date:

DOB: 28/11/1920

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia	Required Visit to Doctor	Hyperextension of neck - difficulty with swallowing.	
Musculoskeletal stiffness	Required Visit to Doctor	Hyperextension of neck - difficulty with swallowing.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis
5.0 Milligram	Daily
Batch:	Started: 24/09/2002 Stopped: 04/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Principal diagnosis = Dementia. Allergies to Penicillin, Tetracycline and Sulphur. On concomitant antidepressant therapy (Aropax) and anti-epileptic (Valproate).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186276 **Seq:** 1 **Gender:** U
Reported: 28/05/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 47
Onset Date: 08/03/2003 **DOB:** 23/02/1956
Outcome: Recovered 09/03/2003 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia Consciousness fluctuating Dysgraphia Polydipsia Somnolence		Hyponatraemia, polydypsia, consciousness fluctuating, drowsiness, writing movements.	Fluid restriction.

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)		Reason: Diabetes mellitus	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified neurosis	
	40.0 Milligram	Daily	
Batch:	Started: 08/03/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/05/2003	Serum glucose		08/03/2003	10.8	
28/05/2003	Serum glucose		09/03/2003	5.1	
28/05/2003	Sodium		08/03/2003	123	
28/05/2003	Sodium		09/03/2003	141	

Additional Information:

History: Chronic schizophrenia and NIDDM controlled with Amisulpride and Metformin. Amisulpride ceased and Olanzapine commenced 1 week ago. H2O consumption - 1/2 cup every 20mins. Patient began during compulsivity after switched from Amisulpride to Olanzapine (due to poor tolerance/weight gain).



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186541 **Seq:** 1 **Gender:** M
Reported: 03/06/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 77Y
Onset Date: 25/02/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Postural hypotension.	Decreased dose, changed to Madopar 50/12.5 tds. Celecoxib ceased.

Medicine Details:

LEVODOPA-CARBIDOPA (Suspected)		Reason: Paralysis agitans	
Tablet	3.0 Dose Unspecified Daily	Oral	
Batch:	Started:	Stopped: 28/02/2003	
CELECOXIB (Suspected)		Reason: Pain	
Capsule	400.0 Milligram Daily	Oral	
Batch:	Started:	Stopped: 27/02/2003	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	0.5 Dose Unspecified Daily	Oral	
Batch:	Started:	Stopped: 03/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Sertraline, Gliclazide and Pizotifen.
Standing blood pressure had improved.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186562

Seq: 1

Gender: F

Reported: 03/06/2003

Weight: 80.00

Hospitalisation:

Age: 57

Onset Date: 08/05/2003

DOB: 02/04/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Burning sensation	Required Visit to Doctor	Bilateral lower legs and ankles oedema, redness and burning sensation both lower legs and ankles.	
Erythema	Required Visit to Doctor	Bilateral lower legs and ankles oedema, redness and burning sensation both lower legs and ankles.	
Oedema	Required Visit to Doctor	Bilateral lower legs and ankles oedema, redness and burning sensation both lower legs and ankles.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis		
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 22/04/2003	Stopped: 14/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Clonazepam, Epilium, Temazepam, Sezoquel, panadol.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186583

Seq: 1

Gender: M

Reported: 04/06/2003

Weight: 0.00

Hospitalisation:

Age: 82Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor Fall Muscle rigidity		Unilateral tremors of hand, rigidity, frequent falls	Stopped Efexor XR

Medicine Details:

EFEXOR-XR (Suspected)		Reason: Depression	
Capsule	75.0 Milligram	Daily	Oral
Batch:	Started: 21/11/2002	Stopped:	19/12/2002
OLANZAPINE (Suspected)		Reason:	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 21/11/2002	Stopped:	16/01/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Renitec, Zylprim, Aspirin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186590

Seq: 1

Gender: F

Reported: 04/06/2003

Weight: 0.00

Hospitalisation:

Age: 42Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Abnormal movements of thumb and fingers - tardive dyskinesia. Withdrawal dyskinesia.	

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Lithium, Epilim, Zoloft, Lipitor.

Zyprexa symptoms went when dose increased to 5mg again, because of breakthrough psychotic symptoms.

Zyprexa dose was reduced to 2.5mg sometime in August 2002. Symptoms occurred sometime in September 2002.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186595

Seq: 1

Gender: M

Reported: 04/06/2003

Weight: 0.00

Hospitalisation:

Onset Date: 21/05/2003

Age: 23

DOB: 02/07/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Stevens-Johnson syndrome		Stevens-Johnson syndrome: oral mucosa / penile mucosa / conjunctiva nasal mucosa involvement.	Topical steroids/mouthwash/iv fluids support.

Medicine Details:

ZYPREXA (Suspected)	Reason: Depression
Tablet	10.0 Milligram
	Daily
	Oral
Batch:	Started: 20/05/2003
	Stopped: 24/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Mirtazapine, Valium.
Previous 3/12 course of Zyprexa last year-apparently developed mild oral ulceration at time.
No erythema multiforme.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186674 **Seq:** 1 **Gender:** M
Reported: 06/06/2003 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 16/04/2003 **DOB:** 23/06/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetic ketoacidosis		Diabetic ketoacidosis	Commenced on insulin.

Medicine Details:

DIAZEPAM (Other drug)	Reason:
5.0 Milligram	As necessary
Batch:	Started: Stopped:
OLANZAPINE (Suspected)	Reason: Schizophrenia
20.0 Milligram	Daily
Batch:	Started: Stopped: 16/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Olanzapine commenced Oct 2002. In retrospect had raised BSLs prior to discharge from psychiatric ward several weeks after Olanzapine commenced. Not followed.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186687
Reported: 06/06/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 23/05/2003

Age: 94

DOB: 29/04/1909

Outcome: Recovered

02/06/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothermia	Caused or prolonged inpatient hospitalisation	Hypothermia and confusion. Recent confusion and wandering outdoor in cold/wet, detected pesticides containing carbaryl in drug screen.	Olanzapine ceased, bear hugger.
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Hallucinations
2.5 Milligram	Daily
Batch:	Started: 19/05/2003 Stopped: 26/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Fusemide, Thyroxine, Aspirin, pantoprazole, caltrate, Slow k, metoclopramide, Spirondactone, Trimethoprim.
History of Hypothyroidism.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 186770

Seq: 1

Gender: M

Reported: 10/06/2003

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date: 24/02/2003

DOB: 13/09/1959

Outcome: Not yet recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Hyperglycaemia	Ceased Olanzapine.
Hyperlipidaemia		Hyperglycaemia	Ceased Olanzapine.

Medicine Details:

FLUVOXAMINE MALEATE (Interaction)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason: Depression	
	10.0 Milligram	Daily	
Batch:	Started:	S TERM	Stopped: 27/02/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/06/2003	Serum glucose		24/02/2003	38.1	

Additional Information:

Patient was also taking Sodium Valproate, Accdactone, Luvox, Mycrogynon ED.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186880

Seq: 1

Gender: F

Reported: 12/06/2003

Weight: 0.00

Hospitalisation:

Age: 23Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Hepatitis nos, Alanine aminotransferase increased	Ceased Epilim and Olanzapine.
Alanine aminotransferase increase			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped: 29/05/2003	
EPILIM (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 19/05/2003	Stopped: 29/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186914

Seq: 1

Gender: F

Reported: 16/06/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus insulin-dependen		NIDDM	Diet which believes manage diabetes.
Weight increased		weight increased	

Medicine Details:

EFEXOR (Other drug)		Reason:	
Tablet		Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/06/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 186915

Seq: 1

Gender: M

Reported: 16/06/2003

Weight: 0.00

Hospitalisation:

Onset Date: 15/05/2003

Age: 23Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Stevens-Johnson syndrome		Stevens Johnson Syndrome	Zyprexa was ceased, treated with Xylocain, Lignocain, Steroid, Antibiotic eye drops, Chlorhexadine mouth wash, IV fluid support.

Medicine Details:

AVANZA (Other drug)		Reason:	
Batch:	Started:	Stopped:	contin
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zyprexa was started and stopped sometime in may 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 187019

Seq: 1

Gender: M

Reported: 18/06/2003

Weight: 0.00

Hospitalisation:

Age: 44

Onset Date:

DOB: 06/01/1959

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depressed mood	Required Visit to Doctor	Patient associates onset of depressed mood.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Schizophrenia
Tablet	2.5 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient strongly associates onset of depressed mood with increased Zyprexa use. His underlying schizo-affective disorder make the association difficult to discern.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 187137

Seq: 1

Gender: M

Reported: 20/06/2003

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Required Specialist Consultation	Weight gain, diabetes mellitus non-insulin-dependent and feeling unwell.	Diet to control weight and blood sugar levels and oral hypoglycaemics.
Diabetes mellitus non-insulin-depe	Required Specialist Consultation		
Malaise	Required Specialist Consultation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
EFEXOR-XR (Other drug)		Reason:	
Oral application		Dose Unspecified	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Schizo-affective type psychos	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 2003. Medical history: Includes chronic psychosis and a history of obesity.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 187692

Seq: 1

Gender: M

Reported: 25/06/2003

Weight: 72.50

Hospitalisation:

Onset Date: 10/06/2003

Age: 52

DOB: 27/03/1951

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia	Required Visit to Doctor	Diffuse soft lump under right nipple.	

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started: 11/12/2002	Stopped:	Contin
OLANZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 27/02/2003	Stopped: 02/05/2003	
OLANZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 02/05/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 187726

Seq: 1

Gender: F

Reported: 25/06/2003

Weight: 121.00

Hospitalisation:

Age: 30

Onset Date: 15/07/2001

DOB: 26/02/1971

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Required Visit to Doctor	Diabetes mellitus and mild hyperglycaemia.	Metformin. Zyprexa ceased.
Hyperglycaemia	Required Visit to Doctor	Diabetes mellitus and mild hyperglycaemia.	

Medicine Details:

ZYPREXA (Suspected)		Reason: Schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 15/05/2001	Stopped: 26/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Thyroxine, Sodium Valproate and Fluoxetine.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 188147

Seq: 1

Gender: M

Reported: 03/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 25/05/2003

Age: 30

DOB: 02/05/1973

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	Peripheral oedema bilaterally, skin hot and red.	Oral antibiotics. Olanzapine ceased.
Cellulitis	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Wafer	30.0 Milligram	Daily	Oral
Batch:	Started: 15/05/2003	Stopped: 05/06/2003	
CLONAZEPAM (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	6.0 Milligram	Daily	Oral
Batch:	Started: 15/05/2003	Stopped: 20/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/07/2003	Echocardiogram				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188198

Seq: 1

Gender: F

Reported: 02/07/2003

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

19/09/0600

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	Hyponatraemia, peripheral oedema, elevated LFT's.	Ceased Olanzapine and replaced with Risperidone.
Hepatic enzyme increased	Required Visit to Doctor		
Hyponatraemia	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis
	7.5 Milligram	Daily
Batch:	Started: 14/04/2003	Stopped: 05/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Paroxetine, Clonazepam, Ranitidine, Spronolactone, Felodipine.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188210

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 06/05/2003

Age: 56

DOB: 27/08/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaundice cholestatic	Caused or prolonged inpatient hospitalisation	Obstructive jaundice.	
Hepatitis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Zolpidem Sandoz (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 12/05/2003	
OLANZAPINE (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 12/05/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	ALT = SGPT		07/05/2003	1030	
07/07/2003	ALT = SGPT		12/05/2003	1260	
07/07/2003	ALT = SGPT		09/05/2003	1300	
07/07/2003	ALT = SGPT		15/05/2003	915	
07/07/2003	ALT = SGPT		16/05/2003	905	
07/07/2003	AST = SGOT		07/05/2003	1000	
07/07/2003	AST = SGOT		09/05/2003	1340	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188210

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 06/05/2003

Age: 56

Outcome: Not yet recovered

DOB: 27/08/1946

Causality: Causality possible

Reaction Details:

Medicine Details:

Zolpidem Sandoz (Suspected)			Reason:	
Tablet	20.0	Milligram	Daily	Oral
Batch:	Started:	Stopped: 12/05/2003		
OLANZAPINE (Suspected)			Reason:	
Tablet	20.0	Milligram	Daily	Oral
Batch:	Started:	Stopped: 12/05/2003		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	AST = SGOT		12/05/2003	1080	
07/07/2003	AST = SGOT		16/05/2003	662	
07/07/2003	AST = SGOT		15/05/2003	682	
07/07/2003	Bilirubin		07/05/2003	153	
07/07/2003	Bilirubin		09/05/2003	189	
07/07/2003	Bilirubin		12/05/2003	122	
07/07/2003	Bilirubin		16/05/2003	72	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188210

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 06/05/2003

Age: 56

DOB: 27/08/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

Zolpidem Sandoz (Suspected)			Reason:	
Tablet	20.0	Milligram	Daily	Oral
Batch:	Started:		Stopped:	12/05/2003
OLANZAPINE (Suspected)			Reason:	
Tablet	20.0	Milligram	Daily	Oral
Batch:	Started:		Stopped:	12/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	Bilirubin		15/05/2003	82	
07/07/2003	GGT = SGGT =		07/05/2003	586	
07/07/2003	GGT = SGGT =		09/05/2003	624	
07/07/2003	GGT = SGGT =		12/05/2003	562	
07/07/2003	GGT = SGGT =		16/05/2003	620	
07/07/2003	GGT = SGGT =		15/05/2003	542	
07/07/2003	Liver biopsy				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188210

Seq: 1

Gender: M

Reported: 07/07/2003

Weight: 0.00

Hospitalisation:

Age: 56

Onset Date: 06/05/2003

DOB: 27/08/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

Zolpidem Sandoz (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	Started:	Stopped: 12/05/2003			

OLANZAPINE (Suspected)			Reason:		
Tablet	20.0	Milligram	Daily	Oral	
Batch:	Started:	Stopped: 12/05/2003			

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2003	SAP = ALP		07/05/2003	335	
07/07/2003	SAP = ALP		09/05/2003	366	
07/07/2003	SAP = ALP		12/05/2003	349	
07/07/2003	SAP = ALP		15/05/2003	327	
07/07/2003	SAP = ALP		16/05/2003	363	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 188258
Reported: 09/07/2003
Hospitalisation:
Onset Date: 25/08/2002
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 76
DOB: 14/03/1926
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia Anaemia Diarrhoea Platelet count decreased Pyrexia		Admitted to hospital for investigation of pancytopenia associated with fevers and diarrhoea.	Treated empirically with Timentin and Ciprofloxacin. G-CSF 300mcg given as a single dose, with patient responding readily with a rise in WCC. Clopidogrel and Olanzapine ceased.

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	2.5 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 25/08/2002	
CLOPIDOGREL (Suspected)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2002	Stopped: 25/08/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2003	Haemoglobin		14/08/2002	101	
09/07/2003	Haemoglobin		23/08/2002	103	
09/07/2003	Haemoglobin		25/08/2002	92	
09/07/2003	Haemoglobin		26/08/2002	95	
09/07/2003	Haemoglobin		30/08/2002	124	
09/07/2003	Haemoglobin		02/09/2002	127	
09/07/2003	Platelets		14/08/2002	258	

Additional Information:

Patient also taking Metoprolol, Tradolpril, Simvastatin, Aspiring, Timolol 0.5% eye drops and Carbechol eye drops.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188258
Reported: 09/07/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 25/08/2002

Age: 76

DOB: 14/03/1926

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	2.5 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 25/08/2002	

CLOPIDOGREL (Suspected)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2002	Stopped: 25/08/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2003	Platelets		23/08/2002	190	
09/07/2003	Platelets		26/08/2002	210	
09/07/2003	Platelets		02/09/2002	315	
09/07/2003	Platelets		30/08/2002	227	
09/07/2003	Platelets		25/08/2002	101	
09/07/2003	White blood cells		14/08/2002	6.11	
09/07/2003	White blood cells		23/08/2002	0.84	

Additional Information:

Patient also taking Metoprolol, Tradolopril, Simvastatin, Aspiring, Timolol 0.5% eye drops and Carbechol eye drops.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188258

Seq: 1

Gender: F

Reported: 09/07/2003

Weight: 0.00

Hospitalisation:

Age: 76

Onset Date: 25/08/2002

DOB: 14/03/1926

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	2.5 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 25/08/2002	

CLOPIDOGREL (Suspected)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2002	Stopped: 25/08/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2003	White blood cells		25/08/2002	0.46	
09/07/2003	White blood cells		26/08/2002	0.92	
09/07/2003	White blood cells		30/08/2002	2.02	
09/07/2003	White blood cells		02/09/2002	13.4	

Additional Information:

Patient also taking Metoprolol, Tradolopril, Simvastatin, Aspiring, Timolol 0.5% eye drops and Carbechol eye drops.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188333

Seq: 1

Gender: F

Reported: 09/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 09/03/2003

Age: 37

DOB: 08/09/1965

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity		Hypersensitivity	
Liver function test abnormal		Hypersensitivity with rash, fever and raised LFT's.	
Pyrexia		Hypersensitivity with rash, fever and raised LFT's.	
Rash		Hypersensitivity with rash, fever and raised LFT's.	

Medicine Details:

PHENYTOIN SODIUM (Suspected)		Reason: Epilepsy	
	400.0 Milligram	Daily	
Batch:	Started: 15/02/2003	Stopped: 10/03/2003	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.5 Milligram	Alternate days	Oral
Batch:	Started:	Stopped: 10/03/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/07/2003	ALT = SGPT				
09/07/2003	Albumin				
09/07/2003	GGT = SGGT =		10/03/2003	215	
09/07/2003	Other data				

Additional Information:

Other drugs: Methadone, Baclofen, Thiamine, Sorbitol and Coloxyl.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188553
Reported: 17/07/2003

Seq: 1

Gender: M
Weight: 68.00

Hospitalisation:

Onset Date: 04/11/2002

Age: 15

DOB: 13/03/1987

Outcome: Recovered

18/11/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Malaise	Caused or prolonged inpatient hospitalisation	malaise, fevers, delerium, muscles aches, creatine kinase increased.	Ceased Risperidone and Olanzapine.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Myalgia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 25/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/07/2003	Creatine				

Additional Information:

History of intellectual and global speeches delay.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188553

Seq: 1

Gender: M

Reported: 17/07/2003

Weight: 68.00

Hospitalisation:

Age: 15

Onset Date: 04/11/2002

DOB: 13/03/1987

Outcome: Recovered

18/11/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 25/10/2002	

Laboratory Investigations:

Additional Information:

History of intellectual and global speeches delay.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 188596

Seq: 1

Gender: F

Reported: 14/07/2003

Weight: 60.00

Hospitalisation:

Age: 26

Onset Date: 03/04/2003

DOB: 25/01/1977

Outcome: Recovered

10/04/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Generalised oedema	Required Visit to Doctor	Generalised oedema.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	5.0 Milligram Daily Oral
Batch:	Started: 18/03/2002 Stopped: 06/04/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Cipramil and Epilim.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188676

Seq: 1

Gender: M

Reported: 21/07/2003

Weight: 0.00

Hospitalisation:

Onset Date: 27/05/2003

Age: 84

DOB: 22/06/1918

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Required Visit to Doctor	Severe extrapyramidal symptoms, with tremor - generalized, including jaw, tongue, rendering speech unintelligible. Had been coming on for months, severe by 27.5.03.	Zyprexa ceased.
Dysarthria	Required Visit to Doctor		
Tremor	Required Visit to Doctor		

Medicine Details:

ZYPREXA (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	5.0 Milligram Daily Oral
Batch:	Started: 15/07/2001 Stopped: 31/05/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Efexor, Lithicarb, Epilim and Losec.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 188982 **Seq:** 1 **Gender:** F
Reported: 29/07/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 84
Onset Date: 27/06/2003 **DOB:** 25/05/1919
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium Aggression Confusional state Disorientation		Acute delirium, increased confusion, aggression and disorientation.	Zyprexa ceased. Haloperidol injection and tablets were prescribed.

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
Tablet	Daily Oral
Batch:	Started: 16/06/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Avapro, Noten, Zqntac, Pulmicort and Oxis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 188990 **Seq:** 1 **Gender:** F
Reported: 28/07/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 61
Onset Date: 16/02/2003 **DOB:** 15/04/1941
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion Weight decreased Anorexia Liver function test abnormal Red blood cell sedimentation rate i Somnolence		Grand Mal Seizure , Liver Enzyme Abnormal , Anorexia. Weight loss of 14kg over 5 months.	Zyprexa and Haloperidol ceased.

Medicine Details:

ZYPREXA (Suspected)		Reason: Otr spec symp psychopathol nec	
	10.0 Milligram	Daily	Oral
Batch:	Started: 05/09/2002	Stopped:	
HALOPERIDOL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.2 Milligram	Daily	Oral
Batch:	Started: 02/06/2002	Stopped: 16/02/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/07/2003	ALT = SGPT		18/02/2003	246	
28/07/2003	Erythrocyte		18/02/2003	114	
28/07/2003	GGT = SGGT =		18/02/2003	127	
28/07/2003	SAP = ALP		18/02/2003	350	

Additional Information:

Patient also taking sustagen.
History included: Early onset dementia and agitation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 189063

Seq: 1

Gender: F

Reported: 01/08/2003

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 03/07/2003

DOB: 24/08/1956

Outcome: Recovered

18/07/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Blotchy skin	
Vision blurred		Severe blurr vision.	Ceased Zyprexa.
Oedema peripheral		Swelling of extremities.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet	5.0 Milligram Daily Oral
Batch:	Started: 02/07/2003 Stopped: 07/07/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous history of allergy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189091

Seq: 1

Gender: F

Reported: 30/07/2003

Weight: 70.00

Hospitalisation:

Age: 54

Onset Date: 10/07/2003

DOB: 20/05/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Required Visit to Doctor	Blurred vision, dry mouth.	
Dry mouth	Required Visit to Doctor		

Medicine Details:

SEROQUEL (Interaction)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 26/05/2003	Stopped:	
PROTHIADEN (Interaction)		Reason:	
Capsule	25.0 Milligram	Daily	Oral
Batch:	Started: 27/02/2003	Stopped:	
PROTHIADEN (Interaction)		Reason:	
Tablet	75.0 Milligram	Daily	Oral
Batch:	Started: 10/07/2003	Stopped:	
RISPERDAL (Interaction)		Reason:	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 02/09/2002	Stopped: 03/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189091

Seq: 1

Gender: F

Reported: 30/07/2003

Weight: 70.00

Hospitalisation:

Age: 54

Onset Date: 10/07/2003

DOB: 20/05/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Interaction)

Reason:

Tablet

12.5 Milligram

Daily

Oral

Batch:

Started: 02/09/2002

Stopped: 03/06/2003

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 189185 **Seq:** 1 **Gender:** F
Reported: 05/08/2003 **Weight:** 96.00
Hospitalisation: Admitted to hospital **Age:** 32Y
Onset Date: 20/06/2003 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ketoacidosis	Caused or prolonged inpatient hospitalisation	Ketoacidosis, diabetes mellitus precipitated, body weight increased	Insulin Metformin on discharge from hospital.
Diabetes mellitus	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/02/2002	Stopped: 20/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189263

Seq: 1

Gender: F

Reported: 07/08/2003

Weight: 50.00

Hospitalisation:

Age: 48

Onset Date: 31/07/2003

DOB: 12/09/1954

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Severe	Severe skin eruption	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 02/07/2003	Stopped: 28/07/2003	
OLANZAPINE (Suspected)		Reason: Depression	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 09/07/2003	Stopped: 28/07/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189489

Seq: 1

Gender: M

Reported: 14/08/2003

Weight: 0.00

Hospitalisation:

Onset Date: 18/03/2003

Age: 70

DOB: 30/03/1932

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspraxia		Dyspraxia started approx. 10 days after Olanzapine dose increased from 2.5mg nocte to 5mg nocte (approx. 1 month after surgery) by psychiatrist as patient becoming increasingly depressed - flat, irritable, melancholic.	Olanzapine ceased. Bzotropine commenced - 0.5mg bd. Maxolon and Stemetil to be avoided.
Depression			
Tardive dyskinesia			

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
Tablet	5.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Clonazepam, Heparin, Thyroxine, Lamotrigine, Lactulose, Docusate and Senna, Glycerin, Hyoscine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 189528

Seq: 1

Gender: F

Reported: 12/08/2003

Weight: 67.00

Hospitalisation:

Age: 73

Onset Date:

DOB: 16/03/1930

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor	Facial rash	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
	5.0 Milligram	Daily
Batch:	Started:	Stopped: 07/05/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 189773

Seq: 1

Gender: F

Reported: 22/08/2003

Weight: 70.00

Hospitalisation:

Age: 59

Onset Date: 12/08/2003

DOB: 17/04/1944

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Life threatening	Death	
Sudden death	Life threatening	Death unexpected	Found dead at home - autopsy pending.

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	3.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
BENZTROPINE MESYLATE (Suspected)		Reason:	
	2.0 Milligram	Daily	
Batch:	Started:	Stopped:	
LOSEC (Suspected)		Reason:	
Oral application	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
MAGNESIUM NOS (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Long term use of all suspected drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189773

Seq: 1

Gender: F

Reported: 22/08/2003

Weight: 70.00

Hospitalisation:

Age: 59

Onset Date: 12/08/2003

DOB: 17/04/1944

Outcome: Death

Causality: Causality possible

Reaction Details:

Medicine Details:

VALIUM (Suspected)

Reason:

Oral application

5.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

Long term use of all suspected drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189796 **Seq:** 1 **Gender:** M
Reported: 25/08/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 25Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis acute	Caused or prolonged inpatient hospitalisation	Acute pancreatitis.	
Blood cholesterol increased		High cholesterol.	
Weight increased		Weight gain.	

Medicine Details:

ZYPREXA (Suspected)		Reason: Obsessive compulsive neurosis	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason: Obsessive compulsive neurosis	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recommended sertraline hydrochloride at 25mg/day. The reporter believes the events of weight gain and high cholesterol could possibly be related to olanzapine and does not know if the pancreatitis was related to the olanzapine treatment. Date of onset July 2003. Therapy with zyprexa started in April 2003



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 189818
Reported: 25/08/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 38Y

Hospitalisation:

Onset Date: 15/07/2003
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased		Neuroleptic malignant syndrome, body temperature increased, muscle stiffness, joint stiffness, leukocytosis, tachypnoea, sweating	Treatment in hospital included intravenous fluids, intravenous antibiotics and further investigations
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		
Joint stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	contin
ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

About 12 months after taking Olanzapine consistently the patient has experienced Neuroleptic Malignant Syndrome or Serotonergic Syndrome.
Patient was discharged and is under the care of a cardiologist for Myocarditis. The patient is continuing on Olanzapine treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 189818
Reported: 25/08/2003
Hospitalisation:
Onset Date: 15/07/2003
Outcome: Unknown

Seq: 1

Gender: F
Weight: 0.00
Age: 38Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		
Tachypnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Oral application	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	contin
ZOLOFT (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	contin

Laboratory Investigations:

Additional Information:

About 12 months after taking Olanzapine consistently the patient has experienced Neuroleptic Malignant Syndrome or Serotonergic Syndrome.
Patient was discharged and is under the care of a cardiologist for Myocarditis. The patient is continuing on Olanzapine treatment.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 190386 **Seq:** 1 **Gender:** M
Reported: 10/09/2003 **Weight:** 75.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 20/08/2003 **DOB:** 27/12/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Weight increased from 80 kg to 110kg, found to have IDDM.	Mixtard 30/70
Diabetes mellitus	Caused or prolonged inpatient hospitalisation		
Polydipsia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)	Reason: Unspecified psychosis
Batch:	Started: 01/05/2001 Stopped: 28/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking sandomigran, viox.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 190386 **Seq:** 1 **Gender:** M
Reported: 10/09/2003 **Weight:** 75.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 20/08/2003 **DOB:** 27/12/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polyuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis
Batch:	Started: 01/05/2001	Stopped: 28/08/2003

Laboratory Investigations:

Additional Information:

Patient also taking sandomigran, vioxx.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 190481

Seq: 1

Gender: F

Reported: 15/09/2003

Weight: 0.00

Hospitalisation:

Age: 55Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Acute myocarditis	

Medicine Details:

SEROQUEL (Suspected)		Reason: Unspecified schizophrenia	
		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet		20.0 Milligram	
		Daily	
		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/09/2003	Other data				

Additional Information:

The patient had no history of cardiac problems.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 190620

Seq: 1

Gender: M

Reported: 18/09/2003

Weight: 70.00

Hospitalisation:

Age: 23

Onset Date: 10/09/2003

DOB: 20/10/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia	Required Visit to Doctor	Gynaecomastia of the right nipple and another breast lump found in the left breast upper, medial quad.	
Breast mass	Required Visit to Doctor		

Medicine Details:

ZOLOFT (Suspected)		Reason: Depression	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified neurosis	
	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
18/09/2003	Other data				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 190758

Seq: 1

Gender: U

Reported: 23/09/2003

Weight: 0.00

Hospitalisation:

Age: 56

Onset Date: 20/08/2003

DOB: 27/10/1946

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Required Visit to Doctor	Early tardive movements of tongue and lips.	

Medicine Details:

OLANZAPINE (Suspected)	Reason: Unspecified schizophrenia
5.0 Milligram	Daily
Batch:	Started: 01/06/2003 Stopped: 04/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Olanzapine 5mg day. Had been as high as 15mg.
Worsening on cessation now improved largely resolved in 3 weeks.
Other drugs taken: Valproate, Nitrazepam.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 190793

Seq: 1

Gender: F

Reported: 23/09/2003

Weight: 100.00

Hospitalisation:

Age: 44

Onset Date: 04/09/2003

DOB: 04/02/1959

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema	Required Visit to Doctor	Oedema limbs, increased LFT, felt unwell.	
Liver function test abnormal	Required Visit to Doctor		
Malaise	Required Visit to Doctor		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 19/08/2003	Stopped: 02/09/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Efexor XR, Xanax, Triphasil, Avapro.
First exposure to an antipsychotic.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 191134
Reported: 07/10/2003
Hospitalisation:
Onset Date: 28/08/2003
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 53
DOB: 14/05/1950
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Condition aggravated		Worsening of pre-existing prolongation of QT interval on ECG	Olanzapine was ceased and his concomitant haloperidol was reduced from 2.5mg tds to treatment as needed.

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
HALOPERIDOL (Suspected)		Reason:	
	75.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/10/2003	Creatine kinase				
07/10/2003	Electrocardiograph				
07/10/2003	Troponin				

Additional Information:

Patient also administered: Clozaril, Imipramine, Benztropine Mesylate, Atenolol, Clopidogrel.

Prior to recommencing Clozaril, an echocardiogram was performed on 28 Aug 2003 due to his cardiac and hypertension history. This echocardiogram showed features of moderate ischaemic dilated cardiomyopathy, a left ventricular ejection fraction of approximately 35%, and regional wall motion abnormalities consistent with previous extensive anterior, anteroseptal and apical myocardial infarcts. The dilated cardiomyopathy was considered most likely pre-existing and Clozaril was not suspected to have



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 191267

Seq: 1

Gender: F

Reported: 14/10/2003

Weight: 67.00

Hospitalisation:

Age: 26

Onset Date:

DOB: 03/11/1976

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Galactorrhoea	Required Visit to Doctor	Galactorrhoea, following commencement of zyprexa- continued with change to seroquel	

Medicine Details:

CIPRAMIL (Other drug)		Reason: Depression	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: contin
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reaction occurred sometime in 2002. Zyprexa was started sometime in 2002 and stopped sometime in March 2003.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 191350
Reported: 16/10/2003

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 49

Onset Date:

DOB: 31/05/1954

Outcome: Recovered

01/09/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypomania	Required Visit to Doctor	Addition of Olanzapine to Efexor XR and Lithium in a patient in a depressed phase of bipolar disorder (depression present for some years) led to immediate cycling to hypomania. Increase of the Olanzapine worsened her condition.	Changed drug to Thioridazine, increased Lithium, stopped Efexor.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Depression
	5.0 Milligram	Daily
Batch:	Started: 20/05/2003	Stopped: 04/07/2003
LITHIUM CARBONATE (Suspected)		Reason: Depression
Tablet	900.0 Milligram	Daily Oral
Batch:	Started: 21/01/2003	Stopped:
EFEXOR-XR (Suspected)		Reason: Depression
Tablet	450.0 Milligram	Daily Oral
Batch:	Started: 15/06/2002	Stopped: 28/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Last hypomanic during 1996. Since then depressed. Long past history of anorexia nervosa, normal weight since 1996.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 191441

Seq: 1

Gender: M

Reported: 20/10/2003

Weight: 0.00

Hospitalisation:

Age: 24Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional drug misuse Convulsion		Prescribed overdose, seizure.	

Medicine Details:

ANTIDEPRESSANT NOS (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Schizophrenia	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 191490
Reported: 22/10/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 10/10/2003

Age: 43

DOB: 27/01/1960

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism Carpal tunnel syndrome Constipation Tremor		TREMOR, CARPAL TUNNEL SYNDROME, CONSTIPATION	Ceased Olanzapine and changed to Clozapine.

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason:	
Tablet	450.0 Milligram	Daily	Oral
Batch:	Started: 23/01/2002	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 23/01/2002	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 08/03/1999	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Tremor increases if Olanz increase from 20 to 25mg



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 191671

Seq: 1

Gender: F

Reported: 28/10/2003

Weight: 0.00

Hospitalisation:

Age: 47

Onset Date: 21/10/2003

DOB: 19/04/1956

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Caused or prolonged inpatient hospitalisation	Diabetes mellitus	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 19/10/2003	Stopped: 22/10/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 191716

Seq: 1

Gender: M

Reported: 29/10/2003

Weight: 90.00

Hospitalisation:

Age: 22

Onset Date: 28/10/2003

DOB: 14/02/1981

Outcome: Recovered

01/10/2002

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thinking abnormal	Treated in outpatient department only	Poverty of thought.	
Somnolence	Treated in outpatient department only	Severe somnolence, akathisia, weight gain, blurred vision, dry mouth,	Changed to Risperdal
Akathisia			
Dry mouth			
Vision blurred			
Weight increased			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2002	Stopped: 01/10/2002	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Weight loss, now 82kg, not sleeping 20hours a day.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 191758

Seq: 1

Gender: F

Reported: 30/10/2003

Weight: 75.00

Hospitalisation:

Age: 20

Onset Date: 06/08/2003

DOB: 05/04/1983

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Required Visit to Doctor	Neutropenia x 6 daily treatment.	
Weight increased	Required Visit to Doctor	Weight gain - 65kg at commencement - 75kg at cessation.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
		Dose Unspecified Daily	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
		Dose Unspecified Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 191911

Seq: 1

Gender: F

Reported: 06/11/2003

Weight: 70.00

Hospitalisation:

Age: 28

Onset Date: 06/10/2003

DOB: 11/10/1974

Outcome: Recovered

21/10/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Generalised oedema	Required Visit to Doctor	Acute generalised oedema	Zyprexa ceased. Frusemide 10mg daily x 3 days.

Medicine Details:

ZYPREXA (Suspected)	Reason:
	2.5 Milligram Daily
Batch:	Started: 03/10/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No previous exposure to Zyprexa.
Symptoms appeared after 3 days.
Allergic to MSG.
Other drugs taken: Cipramil, Valium.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 191997
Reported: 10/11/2003

Seq: 1

Gender: M
Weight: 0.00
Age: 75Y

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
HALOPERIDOL (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History included: Agitation and dementia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 192448
Reported: 24/11/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 29Y

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome neonatal	Caused or prolonged inpatient hospitalisation	Drug withdrawal syndrome neonatal, drug exposure during pregnancy.	Dextrose infusion, antibiotic therapy
Drug exposure during pregnancy	Caused or prolonged inpatient hospitalisation		
Hypertonia neonatal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/11/2003	Other data				
24/11/2003	Other data				

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724
Nordeng H and Spigset O. Treatment with selective serotonin re-uptake inhibitors in the third trimester of pregnancy. Drug Safety 2005; 28(7):556-581



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192448
Reported: 24/11/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 29Y

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypoglycaemia neonatal	Caused or prolonged inpatient hospitalisation		
Opisthotonus	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724
Nordeng H and Spigset O. Treatment with selective serotonin re-uptake inhibitors in the third trimester of pregnancy. Drug Safety 2005; 28(7):556-581



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192448

Seq: 1

Gender: F

Reported: 24/11/2003

Weight: 0.00

Hospitalisation:

Age: 29Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor neonatal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Additional Information:

Jaiswal S et al. Paroxetine withdrawal in a neonate with historical and laboratory confirmation. Eur J. Pediatr, 2003, 162, 723-724
Nordeng H and Spigset O. Treatment with selective serotonin re-uptake inhibitors in the third trimester of pregnancy. Drug Safety 2005; 28(7):556-581



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 192453

Seq: 1

Gender: U

Reported: 23/10/2003

Weight: 0.00

Hospitalisation:

Age: 83

Onset Date: 24/06/2003

DOB: 10/07/1919

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Miosis		Pin- point pupils	Ceased Olanzapine.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Reactive confusion	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 18/06/2003	Stopped: 24/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Digoxin.
History of hypothyroidism.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 192469

Seq: 1

Gender: F

Reported: 25/11/2003

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date:

DOB: 03/11/1953

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Caused or prolonged inpatient hospitalisation	Symptoms of polydypsia, polyuria, nocturia for over 6 months and weight gain. BGL 36.5	Insulin and diabetes eduration
Nocturia	Caused or prolonged inpatient hospitalisation		
Polydipsia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	18/11/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Other data				

Additional Information:

Other drugs used : Epilim, Oroxine, Somac and Lithicarb.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 192469

Seq: 1

Gender: F

Reported: 25/11/2003

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date:

DOB: 03/11/1953

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polyuria	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	18/11/2003

Laboratory Investigations:

Additional Information:

Other drugs used : Epilim, Oroxine, Somac and Lithicarb.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192477 **Seq:** 1 **Gender:** F
Reported: 25/11/2003 **Weight:** 45.00
Hospitalisation: Admitted to hospital **Age:** 64
Onset Date: 19/10/2003 **DOB:** 27/04/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome.	Rehydrate.Cease olanzapine. Diazepam 2mg tds iv prn. W/h lithium. Icu r/v, supportive Rx. Forced Na diuresis.
Agitation	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)		Reason: Unspecified psychosis
	10.0 Milligram Daily	
Batch:	Started: 17/10/2003	Stopped: 20/10/2003
LITHIUM CARBONATE (Interaction)		Reason:
	500.0 Milligram Daily	
Batch:	Started:	Stopped: 20/10/2003
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec
	15.0 Milligram Daily	
Batch:	Started: 10/07/2003	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Creatine		27/10/2003	2107	
25/11/2003	Creatine		26/10/2003	1955	
25/11/2003	Creatine		26/10/2003	2133	
25/11/2003	Creatine		24/10/2003	800	
25/11/2003	Creatine		21/10/2003	1107	
25/11/2003	Creatine		05/11/2003	91	
25/11/2003	Creatine		02/11/2003	628	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192477 **Seq:** 1 **Gender:** F
Reported: 25/11/2003 **Weight:** 45.00
Hospitalisation: Admitted to hospital **Age:** 64
Onset Date: 19/10/2003 **DOB:** 27/04/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)		Reason: Unspecified psychosis
	10.0 Milligram Daily	
Batch:	Started: 17/10/2003	Stopped: 20/10/2003
LITHIUM CARBONATE (Interaction)		Reason:
	500.0 Milligram Daily	
Batch:	Started:	Stopped: 20/10/2003
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec
	15.0 Milligram Daily	
Batch:	Started: 10/07/2003	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Creatine		31/10/2003	1385	
25/11/2003	Creatine		29/10/2003	2957	
25/11/2003	Creatine		28/10/2003	2222	
25/11/2003	Creatine		30/10/2003	2983	
25/11/2003	Creatine		01/11/2003	1413	
25/11/2003	Creatine		03/11/2003	375	
25/11/2003	Creatine		07/11/2003	54	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192477 **Seq:** 1 **Gender:** F
Reported: 25/11/2003 **Weight:** 45.00
Hospitalisation: Admitted to hospital **Age:** 64
Onset Date: 19/10/2003 **DOB:** 27/04/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		
Hyperreflexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)		Reason: Unspecified psychosis
	10.0 Milligram Daily	
Batch:	Started: 17/10/2003	Stopped: 20/10/2003
LITHIUM CARBONATE (Interaction)		Reason:
	500.0 Milligram Daily	
Batch:	Started:	Stopped: 20/10/2003
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec
	15.0 Milligram Daily	
Batch:	Started: 10/07/2003	Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Creatine		23/10/2003	656	
25/11/2003	Creatine		25/10/2003	632	
25/11/2003	Serum drug level				

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192477 **Seq:** 1 **Gender:** F
Reported: 25/11/2003 **Weight:** 45.00
Hospitalisation: Admitted to hospital **Age:** 64
Onset Date: 19/10/2003 **DOB:** 27/04/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertonia	Caused or prolonged inpatient hospitalisation		
Incoherent	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)		Reason: Unspecified psychosis
	10.0 Milligram Daily	
Batch:	Started: 17/10/2003	Stopped: 20/10/2003
LITHIUM CARBONATE (Interaction)		Reason:
	500.0 Milligram Daily	
Batch:	Started:	Stopped: 20/10/2003
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec
	15.0 Milligram Daily	
Batch:	Started: 10/07/2003	Stopped: contin

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192477 **Seq:** 1 **Gender:** F
Reported: 25/11/2003 **Weight:** 45.00
Hospitalisation: Admitted to hospital **Age:** 64
Onset Date: 19/10/2003 **DOB:** 27/04/1939
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Interaction)		Reason: Unspecified psychosis
	10.0 Milligram	Daily
Batch:	Started: 17/10/2003	Stopped: 20/10/2003
LITHIUM CARBONATE (Interaction)		Reason:
	500.0 Milligram	Daily
Batch:	Started:	Stopped: 20/10/2003
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec
	15.0 Milligram	Daily
Batch:	Started: 10/07/2003	Stopped: contin

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 192552

Seq: 1

Gender: F

Reported: 27/11/2003

Weight: 0.00

Hospitalisation:

Onset Date: 21/08/2003

Age: 87Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence	Caused or prolonged inpatient hospitalisation	Very drowsy gradual deterioration now doesn't recognise, hypothermia.	Zyprexa ceased.
Cognitive disorder	Caused or prolonged inpatient hospitalisation		
Hypothermia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis
Tablet	2.5 Milligram
	Daily
	Oral
Batch:	Started: 13/08/2003
	Stopped: 22/08/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/11/2003	Other data				

Additional Information:

Patient also administered: Pepcidine, Nitrodur Patch, Aspirin, Tenormin, Coloxyl & Senna.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 192757

Seq: 1

Gender: M

Reported: 02/12/2003

Weight: 0.00

Hospitalisation:

Age: 56Y

Onset Date: 15/11/2003

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe	Caused or prolonged inpatient hospitalisation	Type II diabetes mellitus.	Olanzapine has discontinued.

Medicine Details:

ZYPREXA (Suspected)	Reason:
Tablet	5.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs used: Atorvastatin and Efexor.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 192760
Reported: 02/12/2003

Seq: 1

Gender: F
Weight: 0.00
Age: 76Y

Hospitalisation:

Onset Date: 27/06/2003

DOB:

Outcome: Recovered

11/07/2003

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Life threatening	Acute deterioration in glycaemic control resulting in hyperosmolar coma and seizure generalised tonic clonic.	Intubated, ventilated, benzodiazepines for seizure. ICU admission - noradrenaline and actrapid infusion. Olanzapine ceased - changed to amisulpride
Diabetic coma	Life threatening	Hyperosmolar (non-ketonic) coma	
Blood glucose increased	Life threatening		

Medicine Details:

ZYPREXA (Suspected)	Reason: Paranoia
	1.0 Dose Unspecified Daily
Batch:	Started: 23/06/2003 Stopped: 27/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2003	Lactate		27/06/2003	7.9	
02/12/2003	Other data				
02/12/2003	Serum glucose		27/06/2003	75.6	
02/12/2003	Serum osmolality		27/06/2003	379	

Additional Information:

Patient also administered: Panamax, Novorapid, Protaphane, Coversyl, Vioxx, Transiderm Nitro, Zocor, Celebrex.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 193140

Seq: 1

Gender: F

Reported: 15/12/2003

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Type II diabetes mellitus	Prescribed metformin and blood sugar levels have been well controlled. Ceased Zyprexa.

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had been taking Olanzapine for several years and about 12 months ago she developed Type 11 diabetes. Zyprexa was stopped sometime in Sep 2003.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 193175
Reported: 16/12/2003

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 27/09/2002

Age: 27

DOB: 07/10/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polyserositis	Caused or prolonged inpatient hospitalisation	Polyserositis and pericardial effusion.	Pericardial drain was inserted, transferred to ICU, antibiotics. Clozapine and Olanzapine ceased
Cardiac tamponade	Caused or prolonged inpatient hospitalisation		
Cardiomegaly	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)		Reason:	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2002	Stopped:	11/10/2002
OLANZAPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	08/10/2002

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/12/2003	Echocardiogram				
16/12/2003	Other data				

Additional Information:

Patient also administered: Clozapine, Sodium Valproate, Lithium SR, Salbutamol MDI, Frusemide.
Patient was re-admitted. Increased shortness of breath. Had been taking Olanzapine 10mg nocte since discharge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 193175

Seq: 1

Gender: M

Reported: 16/12/2003

Weight: 0.00

Hospitalisation:

Onset Date: 27/09/2002

Age: 27

DOB: 07/10/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		
Cough	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)		Reason:	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2002	Stopped:	11/10/2002
OLANZAPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	08/10/2002

Laboratory Investigations:

Additional Information:

Patient also administered: Clozapine, Sodium Valproate, Lithium SR, Salbutamol MDI, Frusemide.
Patient was re-admitted. Increased shortness of breath. Had been taking Olanzapine 10mg nocte since discharge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 193175

Seq: 1

Gender: M

Reported: 16/12/2003

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 27/09/2002

DOB: 07/10/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)		Reason:	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2002	Stopped: 11/10/2002	
OLANZAPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 08/10/2002	

Laboratory Investigations:

Additional Information:

Patient also administered: Clozapine, Sodium Valproate, Lithium SR, Salbutamol MDI, Frusemide.
Patient was re-admitted. Increased shortness of breath. Had been taking Olanzapine 10mg nocte since discharge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 193175

Seq: 1

Gender: M

Reported: 16/12/2003

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 27/09/2002

DOB: 07/10/1974

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophilia	Caused or prolonged inpatient hospitalisation		
Pericardial effusion	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Other drug)		Reason:	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2002	Stopped: 11/10/2002	
OLANZAPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 08/10/2002	

Laboratory Investigations:

Additional Information:

Patient also administered: Clozapine, Sodium Valproate, Lithium SR, Salbutamol MDI, Frusemide.
Patient was re-admitted. Increased shortness of breath. Had been taking Olanzapine 10mg nocte since discharge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193478

Seq: 1

Gender: M

Reported: 23/12/2003

Weight: 0.00

Hospitalisation:

Age: 26Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Caused or prolonged inpatient hospitalisation	Intentional overdose, delirium.	
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified septicemia
10.0 Milligram	Daily
Batch:	Started:
	Stopped: Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient took an intentional overdose 200mg of Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193596

Seq: 1

Gender: M

Reported: 06/01/2004

Weight: 0.00

Hospitalisation:

Age: 77

Onset Date: 11/12/2003

DOB: 25/03/1926

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Increased Confusion,	Saw psychologist for Olanzapine.
Hallucination, visual	Caused or prolonged inpatient hospitalisation	Increased visual hallucination.	
Paradoxical drug reaction	Caused or prolonged inpatient hospitalisation	Paradoxical effect, GI Bleed.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193596

Seq: 1

Gender: M

Reported: 06/01/2004

Weight: 0.00

Hospitalisation:

Age: 77

Onset Date: 11/12/2003

DOB: 25/03/1926

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance	Caused or prolonged inpatient hospitalisation	Very stiff and unsteady shuffling gait.	
Gastrointestinal haemorrhage	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193693
Reported: 08/01/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 15/12/2003

Age: 76

DOB: 15/02/1927

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	peripheral oedema (swelling of the leg)	cessation of olanzapine & commencement of Lasix 40mg bd; (N.B. This patient was already in the hospital when peripheral oedema occurred. He had been waiting for nursing home placement for weeks & therefore, the ADR may not be associated with prolonged hospital stay.)

Medicine Details:

ATENOLOL (Other drug)		Reason:	
Tablet	50.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	
PANTOPRAZOLE (Other drug)		Reason:	
Tablet	40.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	
CITALOPRAM HYDROBROMIDE (Other drug)		Reason:	
Tablet	20.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	
HALOPERIDOL (Other drug)		Reason:	
Tablet	0.5 Milligram	1 time	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193693

Seq: 1

Gender: M

Reported: 08/01/2004

Weight: 0.00

Hospitalisation:

Age: 76

Onset Date: 15/12/2003

DOB: 15/02/1927

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

Medication Details:				
THIAMINE (Other drug)			Reason:	
Tablet	100.0	Milligram	1 time	Oral
Batch:	Started:		Stopped:	
OLANZAPINE (Suspected)			Reason:	
Tablet	5.0	Milligram	1 time	Oral
Batch:	Started: 17/11/2003		Stopped: 16/12/2003	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 193766

Seq: 1

Gender: M

Reported: 09/01/2004

Weight: 0.00

Hospitalisation:

Age: 60

Onset Date: 04/10/2003

DOB: 19/01/1943

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Admitted unable to swallow and history of mask like facies 12/12, dribbling 3/12, festinating gait 6/12, dry mouth 9/12.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
	7.5 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Seretide and Salbutamol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 193779
Reported: 09/01/2004

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 09/11/2003

Age: 32

DOB: 18/10/1971

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		High temperatures - up to 40.4 degrees celcius.	AB's commenced as sepsis - no benefit.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Otr spec symp psychopathol nec	
Wafer	30.0 Milligram	Daily	Oral
Batch:	Started: 06/11/2003	Stopped: 08/11/2003	
OLANZAPINE (Suspected)		Reason: Unspecified neurosis	
Wafer	15.0 Milligram	Daily	Oral
Batch:	Started: 08/11/2003	Stopped: 13/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Bisacodyl, Paracetamol, Ranitidine, Metoclopramide, Morphine/Midazolom, Insulin infusion, Propofol infusion, Timentin, Clexane, Methadone.
A spinal injury patient in ICU. No other obvious source of fevers e.g. sepsis found. Olanzapine commenced 06/11/2003. Temps peaked at 40.4 degrees celcius on 13/11/2003. Olanzapine ceased 13/11/2003 am. Active cooling ceased 14/11/2003 am as temps back down to 37 degrees celcius.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 194066

Seq: 1

Gender: M

Reported: 23/01/2004

Weight: 71.00

Hospitalisation:

Age: 79Y

Onset Date: 11/01/2004

DOB:

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Specialist Consultation	Bilateral pedal oedema	not known yet

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 09/01/2004	Stopped: 23/01/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 194237

Seq: 1

Gender: F

Reported: 03/02/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation	Suicidal ideation, withdrawal reaction.	
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PROZAC (Suspected)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 194415

Seq: 1

Gender: M

Reported: 09/02/2004

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date: 22/01/2004

DOB: 27/09/1971

Outcome: Recovered

31/01/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis acute	Caused or prolonged inpatient hospitalisation	Acute Pancreatitis	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose start - 12/03. Other drugs: Amisulpride, Lithium SR and Venlafaxine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 194510
Reported: 11/02/2004

Seq: 1

Gender: M
Weight: 80.00
Age: 39
DOB: 10/08/1964
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Recovered 03/02/2004

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness	Caused or prolonged inpatient hospitalisation	Restlessness, agitated, anxious, pallor, hyperventilation, shaking (limbs and trunk).	
Agitation	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 22/10/2002	Stopped: 25/11/2003	
EFEXOR-XR (Suspected)		Reason: Depression	
Capsule	75.0 Milligram	Daily	
Batch:	Started: 07/10/2003	Stopped: 25/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Lovan tabs, Alprazolam, Valium.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 194510
Reported: 11/02/2004

Seq: 1

Gender: M
Weight: 80.00
Age: 39
DOB: 10/08/1964
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Recovered 03/02/2004

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperventilation	Caused or prolonged inpatient hospitalisation		
Pallor	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Schizophrenia
	10.0 Milligram Daily	
Batch:	Started: 22/10/2002	Stopped: 25/11/2003
EFEXOR-XR (Suspected)		Reason: Depression
Capsule	75.0 Milligram Daily	
Batch:	Started: 07/10/2003	Stopped: 25/11/2003

Laboratory Investigations:

Additional Information:

Patient also administered: Lovan tabs, Alprazolam, Valium.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 194544
Reported: 12/02/2004

Seq: 1

Gender: F
Weight: 76.00

Hospitalisation:

Onset Date: 02/02/2004

Age: 61

DOB: 27/12/1942

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pustular	Caused or prolonged inpatient hospitalisation	Pustular skin eruption and petechies on both legs.	Rofecoxib, dexamethasone, olanzapine stopped.
Petechiae	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Liquid, multipurpose	2.5 Milligram	As necessary	
Batch:	Started:	Stopped:	
ROFECOXIB (Suspected)		Reason:	
	25.0 Milligram	Daily	
Batch:	Started:	Stopped:	
DEXAMETHASONE (Suspected)		Reason:	
	0.5 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drug therapy pantoprazole, paracetamol, morphine, gabapentin, ketamine, venlafaxine, temazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 194678

Seq: 1

Gender: M

Reported: 16/02/2004

Weight: 70.00

Hospitalisation:

Age: 80Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Elevated LFT's.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
	7.5 Milligram	Daily	
Batch:	Started: 21/01/2004	Stopped: 02/02/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 194867

Seq: 1

Gender: M

Reported: 24/02/2004

Weight: 0.00

Hospitalisation:

Age: 16Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure	

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis
Tablet	Dose Unspecified Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset 2004. Dose start date: 2004. Medical condition: Eating disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 194881

Seq: 1

Gender: M

Reported: 25/02/2004

Weight: 70.00

Hospitalisation:

Age: 65

Onset Date: 09/01/2004

DOB: 26/11/1938

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eosinopenia	Required Visit to Doctor	Eosinophilia	Ceased Olanzapine

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 30/01/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/02/2004	Eosinophils	(0.02-.50)	09/01/2004	5.9	
25/02/2004	Eosinophils	(0.02-.50)	06/02/2004	0.66	

Additional Information:

Patient was also taking Sodium Valproate, Lithium Carborate, Aspirin, Simvastatin.
Patient asymptomatic no other causes apparent.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 195196
Reported: 08/03/2004

Seq: 1

Gender: F
Weight: 0.00
Age: 99u

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Caused or prolonged inpatient hospitalisation	Diabetes mellitus, diabetic coma.	
Diabetic coma	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason:
	Dose Unspecified Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No history of diabetes. It is not known if the patient received corrective treatment for the event. Olanzapine was discontinued and the patient was discharged from hospital with no other medications. The event is not continuing and the patient has fully recovered.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 195198 **Seq:** 1 **Gender:** F
Reported: 08/03/2004 **Weight:** 0.00
Hospitalisation: Treated in outpatient department only. **Age:** 51
Onset Date: **DOB:** 12/03/1952
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Required Specialist Consultation	Prescribed overdose, neutrophil count decreased.	Treatment changed to Quetiapine 900mg/daily.
Neutrophil count decreased	Required Specialist Consultation		

Medicine Details:

ZYPREXA (Suspected)		Reason: Schizophrenia	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/03/2004	Neutrophils		18/06/2003	1.5	
08/03/2004	Neutrophils		25/07/2003	1.6	
08/03/2004	Neutrophils		15/08/2003	1.9	
08/03/2004	Neutrophils		01/10/2003	1.9	

Additional Information:

Onset date 1999. Dose start and stop date: 1999 and 06/2003. History: Schizophrenia. Patient prescribed Zyprexa 40mg/daily normal dose is 20mg/daily. The patient was seen by a haematologist on 09/07/03 who believed the neutropenia may have been a dose dependant effect. The patient has not yet recovered. Treatment with Olanzapine was discontinued and treatment changed to Quetiapine 900mg/day but neutropenia persisted, described as unrelated to the Quetiapine treatment.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 195243

Seq: 1

Gender: F

Reported: 10/03/2004

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date: 21/02/2004

DOB: 05/11/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	Delirium, acute confusional state.	3 lots of ECT treatment both sides.
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

STILNOX (Suspected)	Reason: Specific disorders of sleep
Tablet	20.0 Milligram Daily
Batch:	Started: Stopped:
OLANZAPINE (Suspected)	Reason: Unspecified psychosis
10.0 Milligram Daily	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also administered: Efexor, Lithium.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 195245 **Seq:** 1 **Gender:** F
Reported: 10/03/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged	Life threatening	Electrocardiogram QT prolonged, hypokalemia, infarction (near fatal), ventricular tachyarrhythmia.	
Hypokalaemia	Life threatening		
Myocardial infarction	Life threatening		
Ventricular tachycardia	Life threatening		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/03/2004	Potassium	(3.5 - 5.3)			

Additional Information:

The infarct and hypokalemia were life threatening events.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 195537

Seq: 1

Gender: F

Reported: 16/03/2004

Weight: 0.00

Hospitalisation:

Onset Date: 17/01/2003

Age: 35Y

Outcome: Recovered

15/07/2003

DOB:

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash	Required Visit to Doctor	Severe skin burn, blisters in hair line, forehead, cheeks, eyes. Bright yellow blisters which took 5 months to resolve.	Drug ceased by patient.
Blister	Required Visit to Doctor		
Photosensitivity reaction	Required Visit to Doctor		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Zyprexa was started and stopped sometime in January.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 195725

Seq: 1

Gender: M

Reported: 19/03/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date: 04/03/2004

DOB:

Outcome: Not yet recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		Neutrophil count decreased.	Zyprexa ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/03/2004	Neutrophils		04/03/2004	1.0	
19/03/2004	Neutrophils		29/02/2004	3.1	

Additional Information:

History of anorexia; Patient very malnourished, weight less than 40kg. Lowest neutrophil count 1 E9/L. Suspected drug discontinued, event continuing



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 196158

Seq: 1

Gender: F

Reported: 02/04/2004

Weight: 0.00

Hospitalisation:

Onset Date: 19/03/2004

Age: 68Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsion, gait abnormal, Drug ineffective.	
Drug ineffective			
Gait disturbance			

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression	
Tablet	50.0 Milligram		Oral
Batch:	Started:	Stopped:	
EPILIM (Suspected)		Reason:	
	1.5 Gram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	7.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/04/2004	Serum drug level				

Additional Information:

Valproate was reduced to 1000mg on 17/03/04 due to development of unsteady gait. History: Tumor, depression.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 196230
Reported: 05/04/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

31/03/2004

Age: 89
DOB: 21/06/1914
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Colonic pseudo-obstruction	Caused or prolonged inpatient hospitalisation	Pseudo-obstruction of "large bowel", abdominal discomfort, sleeping more, constipation.	Required a visit to doctor. Treated by Agarol.
Abdominal distension	Caused or prolonged inpatient hospitalisation		
Constipation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)	Reason: Unspecified psychosis
Tablet	5.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Onset date: 11/2003. Other drugs: Tritace, Natrilix, Caltrate and Coversyl & Senna.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 196438 **Seq:** 1 **Gender:** F
Reported: 13/04/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 15/03/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pleural effusion	Caused or prolonged inpatient hospitalisation	Patient experienced bilateral pleural effusion, ascites and extended widespread oedema from legs up to sacrum, fingers and face.	Zyprexa ceased.
Ascites	Caused or prolonged inpatient hospitalisation		
Oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason:		
	10.0 Milligram	Daily	Oral
Batch:	Started: 01/03/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient already in hospital.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 196478

Seq: 1

Gender: M

Reported: 15/04/2004

Weight: 60.00

Hospitalisation:

Age: 46Y

Onset Date: 15/05/2003

DOB:

Outcome: Unrelated death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Required Visit to Doctor	Tardive dyskinesia	Lopinavir/Ritonavir bd, Lamivudine 150g bd

Medicine Details:

OLANZAPINE (Suspected)		Reason: Depression
	10.0 Milligram	Daily
Batch:	Started:	L TERM Stopped:
AMITRIPTYLINE HYDROCHLORIDE (Suspected)		Reason: Depression
	25.0 Milligram	Daily
Batch:	Started:	L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient died from HIV 9/12/03. Patient was also taking Valaciclovir, Abacavir, Bactrim and Gabapentin.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 196641 **Seq:** 1 **Gender:** M
Reported: 20/04/2004 **Weight:** 70.00
Hospitalisation: Admitted to hospital **Age:** 55Y
Onset Date: 11/01/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged	Life threatening	Prolonged QTc syndrome, hyponatraemia, 6 min unconscious, collapse.	
Circulatory collapse	Life threatening		
Hyponatraemia	Life threatening		
Loss of consciousness	Life threatening		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
20/04/2004	Sodium	(137-145)			

Additional Information:

Patient was also taking trandilopril, Atenolol, Oxazepime, Aspirin, Thiamine.
past history of prolonged SVT.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 196826 **Seq:** 1 **Gender:** F
Reported: 27/04/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 56
Onset Date: 21/04/2004 **DOB:** 26/01/1948
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Life threatening	Collapse, anxious, hyperventilation, undetectable phosphate levels and cardiac arrest.	ICU admission for 5 days, CPR, phosphate supplementation.
Anxiety	Life threatening		
Blood phosphorus decreased	Life threatening		
Cardiac arrest	Life threatening		
Hyperventilation	Life threatening		

Medicine Details:

ALPRAZOLAM (Suspected)		Reason:	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	Ongoing
OLANZAPINE (Suspected)		Reason:	
		Dose Unspecified	
Batch:	Started:	Stopped:	Ongoing
EFEXOR-XR (Suspected)		Reason: Depression	
Capsule	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Ongoing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/04/2004	Phosphate	0.88 - 1.46	10/04/2004	<0.3	

Additional Information:

Patient hospitalised due to circulatory collapse. Other drug therapy taken: nilstat, aspirin, zyprexa, clexane. Phosphate level decreased with hyperventilation (anxiety), but not sufficient to explain phosphate levels <30.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 196947

Seq: 1

Gender: F

Reported: 13/04/2004

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 18/10/1978

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		Progression of symptoms.	Olanzapine ceased.

Medicine Details:

OLANZAPINE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 196954

Seq: 1

Gender: M

Reported: 03/05/2004

Weight: 0.00

Hospitalisation:

Age: 15Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight increased.	Risperdal ceased and given Olanzapine.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Batch:	Started:	Stopped:	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

On an unspecified date the patient gained 15kg. He was taken off Risperdal and dropped 10kg quickly. He was then put on Olanzapine due to need for an antipsychotic and gained 23kg in 5 weeks.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 197003
Reported: 04/05/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 26/02/2000

Age: 27

DOB: 15/01/1973

Outcome: Death

26/02/2000

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death		Olanzapine toxicity.	

Medicine Details:

FLUVOXAMINE MALEATE (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
ZUCLOPENTHIXOL ACETATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/05/2004	Autopsy report				Post mortem examination conclusion was the cause of death was olanzpine toxicity.. Only a very low level of morphine was indentified in the blood and no monocetylmorphine was found in the urine. These findings effectively exclude heroin toxicity.

Additional Information:

His treatment included electro-convulsive therapy. The patient was prescribed Olanzapine at the rate of 20mg at night. His port-mortem level was 0.5mg per litre, or 580 nonograms per millilitre. The only other time the patient's blood was tested for Olanzapine was on 24 Nov 1999 when the level was 46 nanograms per millilitre. The combination of drugs he was receiving was the same.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197003

Seq: 1

Gender: M

Reported: 04/05/2004

Weight: 0.00

Hospitalisation:

Age: 27

Onset Date: 26/02/2000

DOB: 15/01/1973

Outcome: Death

26/02/2000

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)

Reason:

Tablet

20.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

His treatment included electro-convulsive therapy. The patient was prescribed Olanzapine at the rate of 20mg at night. His post-mortem level was 0.5mg per litre, or 580 nanograms per millilitre. The only other time the patient's blood was tested for Olanzapine was on 24 Nov 1999 when the level was 46 nanograms per millilitre. The combination of drugs he was receiving was the same.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197094
Reported: 07/05/2004

Seq: 1

Gender: F
Weight: 58.00

Hospitalisation:

Onset Date: 08/04/2004
Outcome: Recovered

Age: 26Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	

Medicine Details:

EPILIM (Suspected)		Reason: Neuroses	
Tablet	600.0 Milligram	Daily	Oral
Batch:	Started: 05/04/2004	Stopped: 08/04/2004	
DOXYLIN (Suspected)		Reason: Other acne of sebaceous glands	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started: 24/03/2004	Stopped: 12/04/2004	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 29/03/2004	Stopped: 08/04/2004	
PAXAM (Suspected)		Reason:	
Tablet	1.5 Milligram	Daily	Oral
Batch:	Started: 30/03/2004	Stopped: 19/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/05/2004	Neutrophils		08/04/2004	1.46	
07/05/2004	Neutrophils		11/04/2004	1.27	
07/05/2004	Neutrophils		21/04/2004	3.81	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197180
Reported: 10/05/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 78Y

Hospitalisation:

Onset Date: 31/01/2004
Outcome: Not yet recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence	Caused or prolonged inpatient hospitalisation	Drowsy, low conscious state	Mirtazapine and Olanzapine ceased.
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MIRTAZAPINE (Suspected)		Reason: Depression	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 27/01/2004	Stopped: 30/01/2004	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	1.2 Milligram	Daily	Oral
Batch:	Started: 30/01/2004	Stopped: 30/01/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/05/2004	Other data				

Additional Information:

Patient was also taking Venlafaxine, Aspirin, Lactulose, Coloxyl with Senna, Ostelin, Caltrate, Diamicron, Diabex, Ranitidine, Keflex, Captopril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 197290

Seq: 1

Gender: F

Reported: 12/05/2004

Weight: 50.00

Hospitalisation:

Age: 42

Onset Date: 25/04/2004

DOB: 13/09/1961

Outcome: Recovered

06/05/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropenia	Zyprexa ceased

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 23/04/2004	Stopped: 29/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/05/2004	Neutrophils	6.6	25/04/2004	4.5	
12/05/2004	Neutrophils	6.6	25/04/2004	1.4	
12/05/2004	Neutrophils	6.6	03/05/2004	0.9	

Additional Information:

Patient was also taking Losec and Clexane.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197409
Reported: 17/05/2004

Seq: 1

Gender: F
Weight: 0.00
Age: 88Y

Hospitalisation:

Onset Date:
Outcome: Death

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia	Caused or prolonged inpatient hospitalisation	Swallowing difficult, tardive dyskinesia, widespread rash	Olanzapine was discontinued, treated with Cogentin, benzodiazepines and Narcotics.
Rash generalised	Caused or prolonged inpatient hospitalisation		
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis
Tablet	5.0 Milligram Daily Oral
Batch:	Started: 25/01/2000 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Zoloft, Prednisolone, Losec.
Patient died 12/04/04.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197410

Seq: 1

Gender: F

Reported: 17/05/2004

Weight: 0.00

Hospitalisation:

Age: 73Y

Onset Date: 29/01/2004

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Electrocardiogram QT prolonged	Life threatening	Electrocardiogram QT prolonged and cardiac arrest.	Resuscitation and Olanzapine ceased.
Cardiac arrest	Life threatening		
Electrocardiogram QT prolonged	Life threatening		

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Injection, powder for	10.0 Milligram	3 times	Intramuscular
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 197453

Seq: 1

Gender: M

Reported: 18/05/2004

Weight: 68.00

Hospitalisation:

Age: 62

Onset Date:

DOB: 29/12/1941

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac murmur Cyanosis Hypotension Syncope		Heart murmur - systolic ejection murmur, syncope, hands blue, hypotension.	

Medicine Details:

COVERSYL (Other drug)		Reason:	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	2.5 Milligram	Daily	
Batch:	Started: 22/06/2000	S TERM	Stopped: 12/10/2000

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was taking Olanzapine 1.25mg daily for 6 weeks before the dosage was increased to 2.5mg daily. He was taking Coversyl 4mg daily for 6 weeks before he was decreased to 1mg daily.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 197456

Seq: 1

Gender: M

Reported: 19/05/2004

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 13/04/2004

DOB: 28/11/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Sinus tachycardia Leukocytosis White blood cell count increased		Blood albumin increased, ALT increased. Sinus tachycardia, elevated liver function tests, white blood cell count elevated.	Epilim and Lovan were ceased and Olanzapine was decreased to 20mg/day.

Medicine Details:

EPILIM (Suspected)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
LOVAN (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	225.0 Milligram	Daily	Oral
Batch:	Started: 06/04/2004	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/05/2004	Albumin	35-45	19/04/2004	51	
19/05/2004	Electrocardiograph		13/04/2004	Serial ECG's	
19/05/2004	GGT = SGGT =	7-64	19/04/2004	42	
19/05/2004	Haemoglobin	120-180	19/04/2004	170	
19/05/2004	Platelets	150-450	19/04/2004	251	
19/05/2004	SAP = ALP	30-120	19/04/2004	30	

Additional Information:

Medically significant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 197507 **Seq:** 1 **Gender:** F
Reported: 21/05/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 78Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation	Tardive dyskinesia	

Medicine Details:

DIGOXIN (Other drug)	Reason:
Batch:	Started: Stopped:
FRUSEMIDE (Other drug)	Reason:
Batch:	Started: Stopped:
ASPIRIN (Other drug)	Reason:
Batch:	Started: Stopped:
CLEXANE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Olanzapine, Digoxin, Frusemide, Aspirin and Clexane.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197507 **Seq:** 1

Reported: 21/05/2004

Hospitalisation: Admitted to hospital

Onset Date:

Outcome: Not yet recovered

Gender: F

Weight: 0.00

Age: 78Y

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
EFEXOR (Suspected)		Reason:	
Tablet	412.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: Continuing

Laboratory Investigations:

Additional Information:

Patient also taking Olanzapine, Digoxin, Frusemide, Aspirin and Clexane.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 197670
Reported: 27/05/2004

Seq: 1

Gender: M
Weight: 100.00
Age: 44
DOB: 27/01/1960
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Treated in outpatient department only	Priapism and increased tremor (extrapyramidal side effect) if olanzapine is increased from 20 to 25mg.	Reduction in olanzapine dose. Augmentation with aripiprazole
Priapism	Treated in outpatient department only	Priapism and increased tremor (extrapyramidal side effect) if olanzapine is increased from 20 to 25mg.	Reduction in olanzapine dose. Augmentation with aripiprazole

Medicine Details:

DIAZEPAM (Other drug)	Reason:
2.5 Milligram	2 times Oral
Batch:	Started: 23/01/2002 Stopped:
VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason: Depression
450.0 Milligram	Daily Oral
Batch:	Started: 23/01/2002 L TERM Stopped:
OLANZAPINE (Suspected)	Reason: Schizophrenia
20.0 Milligram	Daily Oral
Batch:	Started: 08/03/1999 L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

symptoms alleviated when olanzapine reduced from from 25 mg to 20 mg



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 197714
Reported: 31/05/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 14/04/2004

Age: 43

DOB: 02/10/1960

Outcome: Recovered

13/05/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	Ceased Zyprexa

Medicine Details:

SOLIAN (Other drug)		Reason: Unspecified psychosis	
Tablet	120.0 Milligram	Daily	Oral
Batch:	Started: 14/01/2004	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 14/11/2003	Stopped: 14/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/05/2004	Neutrophils		16/03/2004	1.55	
31/05/2004	Neutrophils		13/04/2004	1.32	
31/05/2004	Neutrophils		13/05/2005	4.2	
31/05/2004	White blood cells		16/03/2004	3.0	
31/05/2004	White blood cells		13/04/2004	2.8	
31/05/2004	White blood cells		13/05/2004	6.0	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 197740

Seq: 1

Gender: F

Reported: 31/05/2004

Weight: 0.00

Hospitalisation:

Age: 75

Onset Date: 15/12/2003

DOB: 23/10/1928

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Optic neuropathy		Patient lost significant vision in the last six months or so from an unknown optic neuropathy. Visual fields have constricted significantly and her vision has deteriorated such that now she sees only perception of light in the right and 6/18 in the left.	Computerised tomography, numerous blood tests and electrophysiological test.
Visual acuity reduced			
Visual field defect			

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified neurosis
10.0 Milligram	Daily
Batch:	Started: 01/01/1999 L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
31/05/2004	Other data				The patient could only see two out of 15 Ishihara colour test plates in the left eye and none in the right. Goldmann visual fields demonstrated marked constriction. An electrophysiological test was conducted, which demonstrated markedly slower small check visual evoked response and also very low amplitudes in the visual evoked response, indicating delayed optic nerve conduction.

Additional Information:

History: Blindness in the right eye from reported Glaucoma, having had bilateral iridencleisis operations approximately 38 years ago. The patient has been blind since that time and had a very dense cataract, which prevented the reporter from commenting on the state of the right optic nerve. The patient developed a cataract in the left eye and had it removed via an intracapsular cataract extraction procedure approximately 35 years ago.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 198141
Reported: 15/06/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 21Y

Hospitalisation:

Onset Date: 15/05/2004
Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		Creatine Kinase increased and blood lactate dehydrogenase increased.	Olanzapine discontinued.
Blood lactate dehydrogenase incre			Olanzapine discontinued.

Medicine Details:

ZYPREXA (Suspected)	Reason: Schizophrenia
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 01/05/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/06/2004	Creatine kinase				
15/06/2004	LDH				

Additional Information:

History: Schizophrenia and Hepatitis C positive.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 198379

Seq: 1

Gender: M

Reported: 22/06/2004

Weight: 0.00

Hospitalisation:

Age: 69Y

Onset Date: 15/03/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism		Parkinsonism.	

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 01/12/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Epilim, Cipramil, Verapamil, Somac, Amiloride, Astrex.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 198546

Seq: 1

Gender: M

Reported: 28/06/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level above therapeutic		Drug toxicity and death.	
Sudden death		Drug toxicity and death.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Schizophrenia
	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 198566

Seq: 1

Gender: F

Reported: 28/06/2004

Weight: 82.00

Hospitalisation:

Age: 43

Onset Date: 26/09/2002

DOB: 08/11/1958

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Required Visit to Doctor	Onset of diabetes and hyperglycaemia.	Patient now on Metformin.
Hyperglycaemia	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Suspected)	Reason: Schizophrenia
10.0 Milligram	Daily
Batch:	Started: 01/08/2001 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/06/2004	Other data				

Additional Information:

Hyperglycaemia diagnosed 12 months after starting Olanzapine. (tests 6 months after were normal).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 198676

Seq: 1

Gender: F

Reported: 02/07/2004

Weight: 0.00

Hospitalisation:

Onset Date: 15/12/2003

Age: 79

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Caused or prolonged inpatient hospitalisation	Parkinsonism.	

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was commenced on 10mg daily, dose was reduced to 5mg and patient experienced symptoms.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198693

Seq: 1

Gender: F

Reported: 05/07/2004

Weight: 75.00

Hospitalisation:

Age: 35

Onset Date: 10/06/2004

DOB: 05/02/1969

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe	Required Visit to Doctor	Developed diabetes type II.	Diet control.

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 14/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198736
Reported: 05/07/2004

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 30

DOB: 15/08/1973

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary hesitation	Required Visit to Doctor	Urinary hesitation/ retention	Patient had a catheter inserted.
Urinary retention	Required Visit to Doctor	Urinary hesitation/ retention	Patient had a catheter inserted.

Medicine Details:

TEMAZE (Suspected)		Reason:	
	10.0 Milligram	As necessary	Oral
Batch:	Started: 29/06/2004	Stopped:	
ZYPREXA (Suspected)		Reason:	
	10.0 Milligram	Daily	Oral
Batch:	Started: 30/06/2004	Stopped:	
EPILIM (Suspected)		Reason:	
	1000.0 Milligram	Daily	Oral
Batch:	Started: 29/06/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198737

Seq: 1

Gender: F

Reported: 05/07/2004

Weight: 55.00

Hospitalisation:

Age: 44

Onset Date:

DOB: 17/09/1959

Outcome: Recovered without treatment

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Required Visit to Doctor	Swelling of ankles and feet with itching and discomfort. Area not hot to touch	
Discomfort	Required Visit to Doctor	Swelling of ankles and feet with itching and discomfort. Not hot to touch	
Joint swelling	Required Visit to Doctor	Swelling of ankles and feet with itching and discomfort. Not hot to touch	
Pruritus	Required Visit to Doctor	Swelling of ankles and feet with itching and discomfort. Not hot to touch	

Medicine Details:

PAXAM (Other drug)		Reason:	
	0.5 Milligram	Daily	Oral
Batch:	Started: 15/06/2004	Stopped:	
EPILIM (Other drug)		Reason:	
	1500.0 Milligram	Daily	Oral
Batch:	Started: 21/05/2004	Stopped:	
ZYPREXA (Suspected)		Reason:	
	20.0 Milligram	1 time	Oral
Batch:	Started: 24/05/2004	Stopped:	one dose only

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198774

Seq: 1

Gender: F

Reported: 07/07/2004

Weight: 52.50

Hospitalisation:

Age: 57

Onset Date: 15/04/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced deranged liver function tests.	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Schizophrenia	
	15.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2000	Stopped:	
LIPITOR (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2004	AST = SGOT		01/01/1999	46	
07/07/2004	AST = SGOT		15/04/2004	73	
07/07/2004	AST = SGOT		01/07/2004	91	
07/07/2004	GGT = SGGT =		01/01/1999	546	
07/07/2004	GGT = SGGT =		15/04/2004	1049	
07/07/2004	GGT = SGGT =		01/07/2004	1185	
07/07/2004	Other data				

Additional Information:

Other drugs taken: Paracetamol, Thyroxine, Frusemide, Atrovent and Ramipril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198774

Seq: 1

Gender: F

Reported: 07/07/2004

Weight: 52.50

Hospitalisation:

Age: 57

Onset Date: 15/04/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason: Schizophrenia	
	15.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2000	Stopped:	
LIPITOR (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/07/2004	SAP = ALP		01/01/1999	344	
07/07/2004	SAP = ALP		15/04/2004	1146	
07/07/2004	SAP = ALP		01/07/2004	1187	

Additional Information:

Other drugs taken: Paracetamol, Thyroxine, Frusemide, Atrovent and Ramipril.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 198860

Seq: 1

Gender: F

Reported: 12/07/2004

Weight: 50.00

Hospitalisation:

Age: 85

Onset Date: 30/06/2004

DOB: 07/10/1918

Outcome: Recovered

05/07/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coma	Caused or prolonged inpatient hospitalisation	Semicoma - the first one lasting 8 hours and the second lasting over 12+ hours, ??TIA.	Panamax and Polytears.

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Wafer	5.0 Milligram	Daily	Oral
Batch:	Started: 03/06/2004	Stopped: 03/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Astrix, Fosamax, Kalma, Karvezide and Noten.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 198879
Reported: 12/07/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 53

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug interaction Amnesia Confusional state Depression Disorientation Disturbance in attention Hyperhidrosis Myoclonus Serotonin syndrome Suicidal ideation		Drug interaction, serotonin syndrome, depression and suicidal ideation.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)		Reason: Depression	
Capsule	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Continuing
OLANZAPINE (Interaction)		Reason: Depression	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Continuing
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History included recurrent major depressive disorder, generalised anxiety disorder and alcohol dependence in remission. Chopra P, Ng C, Schweitzer I. Serotonin syndrome associated with fluoxetine and Olanzapine. World Journal of Biological Psychiatry. 2004; 5: 114-115. Fluoxetine was stopped, but he was maintained on Olanzapine and Diazepam due to his agitation. Over a week the disorientation, poor concentration, short-term memory and neurological symptoms resolved. After another week he was recommenced on Fluoxetine 20ma in addition to his other medications. There was no observed recurrence of serotonergic or depressive symptoms



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198879
Reported: 12/07/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 53

Hospitalisation:

Onset Date:
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)		Reason: Depression	
Capsule	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Continuing
OLANZAPINE (Interaction)		Reason: Depression	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	Continuing
DIAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

History included recurrent major depressive disorder, generalised anxiety disorder and alcohol dependence in remission. Chopra P, Ng C, Schweitzer I. Serotonin syndrome associated with fluoxetine and Olanzapine. World Journal of Biological Psychiatry. 2004; 5: 114-115. Fluoxetine was stopped, but he was maintained on Olanzapine and Diazepam due to his agitation. Over a week the disorientation, poor concentration, short-term memory and neurological symptoms resolved. After another week he was recommenced on Fluoxetine 20ma in addition to his other medications. There was no observed recurrence of serotonergic or depressive symptoms



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 198959 **Seq:** 1 **Gender:** F
Reported: 15/07/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20
Onset Date: 20/06/2004 **DOB:** 27/12/1983
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Tachycardia, pharyngitis, sweating increased, hypotension.	Clopine ceased.
Hyperhidrosis			
Hypotension	Caused or prolonged inpatient hospitalisation		
Pharyngitis			

Medicine Details:

CLOPINE (Suspected)		Reason:	
Tablet	300.0 Milligram	Daily	Oral
Batch:	Started: 02/06/2004	Stopped: 22/07/2004	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 07/05/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/07/2004	Echocardiogram				Echocardiogram on 26 May and 16 July 2004 showed sinus rhythm, normal cardiac chamber and valves
15/07/2004	Electrocardiograph				ECG noted a sinus tachycardia of 130
15/07/2004	Other data				

Additional Information:

Other drug therapy: valproate, clonazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199033
Reported: 16/07/2004

Seq: 1

Gender: M
Weight: 0.00
Age: 94

Hospitalisation:

Onset Date: 19/08/2001

Outcome: Recovered

19/08/2004

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Respiratory arrest	Life threatening	Patient developed respiratory arrest and altered conscious state (pupils non - reactive).	Nitrazepam, Haopreidol, Tramadol and Panadeine Forte ceased. Naloxone 4mg IV given.
Altered state of consciousness	Life threatening		

Medicine Details:

PANADEINE FORTE (Suspected)		Reason: Pain	
Tablet	1.0 Dose Unspecified	As necessary	Oral
Batch:	Started: 18/08/2001	Stopped: 18/08/2001	
MORPHINE SULPHATE (Suspected)		Reason: Pain	
Injection	2.5 Milligram	As necessary	Intravenous
Batch:	Started: 17/08/2001	Stopped: 18/08/2001	
HALOPERIDOL (Suspected)		Reason: Otr spec symp psychopathol nec	
	2.0 Milligram	Daily	Oral
Batch:	Started: 17/08/2001	Stopped: 18/08/2001	
NITRAZEPAM (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 17/08/2001	Stopped: 18/08/2001	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other drugs taken: Captopril, Thyroxine, Allopurinol and Trimethoprim.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199033

Seq: 1

Gender: M

Reported: 16/07/2004

Weight: 0.00

Hospitalisation:

Age: 94

Onset Date: 19/08/2001

DOB:

Outcome: Recovered

19/08/2004

Causality: Causality possible

Reaction Details:

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected)		Reason: Pain	
	200.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2001	Stopped: 19/08/2001	
OLANZAPINE (Suspected)		Reason: Otr spec symp psychopathol nec	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 18/08/2001	Stopped: 20/08/2001	

Laboratory Investigations:

Additional Information:

Other drugs taken: Captopril, Thyroxine, Allopurinol and Trimethoprim.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 199292

Seq: 1

Gender: M

Reported: 22/07/2004

Weight: 85.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 06/12/1979

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Patient developed orofacial dyskinesia including mouth and tongue movements.	Reduction to 20mg Zyprexa.

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	80.0 Milligram	Daily	Oral
Batch:	Started: 01/05/2003	Stopped: 01/06/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspected drug is dose related.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 199418
Reported: 26/07/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 30/06/2004

Age: 85

Outcome: Recovered

05/07/2004

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation	Semi-coma lasting 8 hours and a transient ischaemic attack.	Olanzapine discontinued
Transient ischaemic attack	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
	5.0 Milligram	Daily	Oral
Batch:	Started: 03/06/2004	Stopped: 03/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History included: Vascular dementia. Olanzapine was withheld and then recommenced and the patient had another episode of semi coma this time lasting 12 hours and the patient was hospitalised. Other drug therapy: astrix, fosamax, noten, panamax.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 199430

Seq: 1

Gender: F

Reported: 27/07/2004

Weight: 58.00

Hospitalisation:

Age: 71

Onset Date: 15/07/2004

DOB: 06/11/1932

Outcome: Recovered

15/07/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination Aggression Agitation		Hallucinations, agitation and aggression.	Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected)		Reason:	
	2.5 Milligram	Daily	
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Aurorix, Caltrate, Neo-cytamen, Panamax, Reminyl, Renitec and Thyroxine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 199503

Seq: 1

Gender: F

Reported: 30/07/2004

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation		Wanted to kill people, went into a frenzy and destroyed shed and wall.	

Medicine Details:

EFEXOR (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 199506

Seq: 1

Gender: F

Reported: 30/07/2004

Weight: 0.00

Hospitalisation:

Age: 45

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mania Suicidal ideation		Became manic and suicidal.	

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started:
	Stopped:
	Oral
	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

OK on SSRI's only. Suspect drug positive rechallenge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199564

Seq: 1

Gender: M

Reported: 30/07/2004

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 20/08/1973

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury		Intentional self harm, cut himself	

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Batch:	Started:	Stopped:	0
EFEXOR (Suspected)	Reason:		
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 199583

Seq: 1

Gender: M

Reported: 02/08/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug toxicity		Drug toxicity	

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199585

Seq: 1

Gender: F

Reported: 02/08/2004

Weight: 0.00

Hospitalisation:

Onset Date: 16/09/2003

Age: 78

Outcome: Death, maybe drug

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Haemorrhagic stroke			

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 11/04/2003	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history included: hypertension and smoking.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199827

Seq: 1

Gender: M

Reported: 10/08/2004

Weight: 78.00

Hospitalisation:

Age: 35

Onset Date: 15/01/2004

DOB: 19/03/1968

Outcome: Recovered

18/01/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Agitation Disturbance in attention Restlessness		Serotonin syndrome, Agitation, loss of concentration and restlessness.	

Medicine Details:

TRAMAL (Interaction)		Reason: Other disturbance of sensation	
	500.0 Milligram	Daily	
Batch:	Started:	Stopped:	0
ZYPREXA (Interaction)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
AVANZA (Other drug)		Reason:	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
STEMETIL (Other drug)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Reduction of Tramadol dose to 400mg/day symptoms settled.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 199827

Seq: 1

Gender: M

Reported: 10/08/2004

Weight: 78.00

Hospitalisation:

Age: 35

Onset Date: 15/01/2004

DOB: 19/03/1968

Outcome: Recovered

18/01/2004

Causality: Causality possible

Reaction Details:

Medicine Details:

VALIUM (Other drug)		Reason:		
Tablet	5.0	Milligram	Daily	Oral
Batch:	Started:		Stopped:	
ZOTON (Other drug)		Reason:		
Capsule	2.0	Dose Unspecified	Daily	Oral
Batch:	Started:		Stopped:	

Laboratory Investigations:

Additional Information:

Reduction of Tramadol dose to 400mg/day symptoms settled.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199855 **Seq:** 1 **Gender:** F
Reported: 10/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Patient experienced hyponatraemia.	

Medicine Details:

AMLODIPINE (Other drug)		Reason:	
Tablet	5.0 Milligram	Oral	
Batch:	Started:	Stopped:	
MULTIVITAMINS (Other drug)		Reason:	
		Oral	
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
		Oral	
Batch:	Started:	Stopped:	
OXAZEPAM (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/08/2004	Sodium				Prior to this reading the patient's sodium level was lower: July 2004 - 130.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199855 **Seq:** 1

Reported: 10/08/2004

Hospitalisation: Admitted to hospital

Onset Date:

Outcome: Not yet recovered

Gender: F

Weight: 0.00

Age: 99u

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

SLOW-K (Other drug)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch: A059086	Started:	Stopped:	Continuing

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199893

Seq: 1

Gender: F

Reported: 11/08/2004

Weight: 0.00

Hospitalisation:

Onset Date: 06/08/2004

Age: 36

DOB: 16/05/1968

Outcome: Recovered

09/08/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Formication		Formication after starting Zyprexa.	

Medicine Details:

ZOLOFT (Other drug)		Reason:	
Tablet	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	26/07/2004
ZYPREXA (Suspected)		Reason:	
Wafer	5.0 Milligram	Daily	Oral
Batch:	Started: 05/08/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: Recalls when took 1 dose of Zyprexa once before, they had formication.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 199921 **Seq:** 1 **Gender:** F
Reported: 12/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 35
Onset Date: 28/07/2004 **DOB:** 24/09/1968
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ebstein's anomaly	Life threatening	Ebstein's anomaly - birth defect second pregnancy.	

Medicine Details:

LITHICARB (Suspected)		Reason:	
	2.0 Gram	Daily	
Batch:	Started: 15/05/1997	Stopped:	
ZYPREXA (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 15/04/2003	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

First pregnancy was taking Lithium - normal infant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 199929
Reported: 12/08/2004

Seq: 1

Gender: M
Weight: 55.00
Age: 99u

Hospitalisation:

Onset Date: 02/08/2004

Outcome: Recovered

05/08/2004

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Required Visit to Doctor	Patient experienced generalised muscle stiffness affecting gait and movement. Spastic appearance rigid with head pulled back.	Cogentin.
Dystonia	Required Visit to Doctor		
Gait disturbance	Required Visit to Doctor		
Muscle rigidity	Required Visit to Doctor		

Medicine Details:

CITALOPRAM HYDROBROMIDE (Suspected)		Reason: Depression
Tablet		Oral
Batch:	Started:	Stopped: 29/07/2004
OLANZAPINE (Suspected)		Reason: Unspecified neurosis
	10.0 Milligram	Daily
Batch:	Started: 22/07/2004	Stopped: 29/07/2004
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason: Depression
	38.0 Milligram	Daily
Batch:	Started: 30/07/2004	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 200414

Seq: 1

Gender: F

Reported: 30/08/2004

Weight: 114.00

Hospitalisation:

Onset Date: 03/07/2004

Age: 62

DOB: 03/04/1942

Outcome: Death, maybe drug

03/07/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Probable fatal cardiac arrhythmia.	

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
10.0 Milligram		Daily	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
Batch:	Started:	Stopped: 30/06/2004	
SOLIAN (Suspected)		Reason: Unspecifid affective psychosis	
400.0 Milligram		Daily	
Batch:	Started: 03/02/2004	Stopped: 03/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 200534 **Seq:** 1 **Gender:** M
Reported: 03/09/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34
Onset Date: 27/08/2004 **DOB:** 10/04/1970
Outcome: Recovered 30/08/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia	Caused or prolonged inpatient hospitalisation	BSL was 39.7, 1 day history of thirst and blurry vision.	Stopped Olanzapine, changed to Risperidone.
Thirst	Caused or prolonged inpatient hospitalisation		
Vision blurred	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)		Reason:	
Injection	1.0	Dose Unspecified	Fortnightly
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Schizophrenia	
	8.0	Milligram	Daily
Batch:	Started: 15/04/2004	Stopped: 15/08/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 200772

Seq: 1

Gender: M

Reported: 13/09/2004

Weight: 75.00

Hospitalisation:

Age: 15

Onset Date: 16/07/2004

DOB: 31/07/1988

Outcome: Recovered

18/07/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash maculo-papular	Required Visit to Doctor	Red, maculo-papular rash on face, neck and chest.	Phenergan 30mg daily given.
Rash erythematous	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 14/07/2004	Stopped: 16/07/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 200850

Seq: 1

Gender: F

Reported: 14/09/2004

Weight: 70.00

Hospitalisation:

Age: 41

Onset Date: 04/08/2004

DOB: 29/03/1963

Outcome: Recovered

01/09/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema	Required Visit to Doctor	Oedema of face, hands, legs and difficulty sleeping.	Ceased Olanzapine.
Insomnia	Required Visit to Doctor		

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason:	
	300.0 Milligram	Daily	
Batch:	Started: 12/09/2002	Stopped:	
OLANZAPINE (Suspected)		Reason: Otr spec symp psychopathol nec	
	5.0 Milligram	Daily Oral	
Batch:	Started: 28/07/2004	Stopped: 25/08/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient Hep B positive; 16 weeks pregnant. Abuse Anphetamines in previous month.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 200941

Seq: 1

Gender: F

Reported: 20/09/2004

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Required Specialist Consultation	The patient experienced changes in liver function, weight gain and she developed diabetes.	
Liver function test abnormal	Required Specialist Consultation		
Weight increased	Required Specialist Consultation		

Medicine Details:

CIPRAMIL (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 201079

Seq: 1

Gender: F

Reported: 23/09/2004

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date: 24/04/2004

DOB: 22/06/1953

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic steatosis		Fatty liver and drug toxicity	
Drug toxicity			

Medicine Details:

RISPERIDONE (Suspected)		Reason: Unspecified schizophrenia	
Injection		Intramuscular	
Batch:	Started: 24/02/2004	S TERM	Stopped: 16/04/2004 0
MIRTAZAPINE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
Zolpidem Sandoz (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 18/03/2004	Stopped:	02/04/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2004	Autopsy report				Severe fatty change in liver and chronic liver disease. Severe diffuse microvesicular fatty changes throughout the liver. Lungs, heart, kidney and brain.

Additional Information:

Chronic liver disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 201344 **Seq:** 1 **Gender:** F
Reported: 29/09/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 90
Onset Date: 15/08/2004 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Dystonia.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Anxiety neurosis
10.0 Milligram	Daily
Batch:	Started: 12/08/2004 Stopped: contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The cause of death was due to drug induced dystonia. The patient's medical history included: delusional state with aggressive behaviour and hypertension.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 201534
Reported: 07/10/2004

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 18/09/2004

Age: 42

DOB: 07/11/1961

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus	Required Visit to Doctor	Patient developed an itchy maculo-papular rash, mainly on lower limbs and trunk.	Olanzapine ceased, topical soothing agent.
Rash maculo-papular	Required Visit to Doctor		

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
CLONAZEPAM (Other drug)		Reason: Unspecifid affective psychosis	
	3.0 Milligram	Daily	
Batch:	Started: 10/09/2004	Stopped:	
NITRAZEPAM (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecifid affective psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 10/09/2004	Stopped: 18/09/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 201542

Seq: 1

Gender: F

Reported: 08/10/2004

Weight: 0.00

Hospitalisation:

Onset Date: 21/09/2004

Age: 57

DOB: 16/10/1946

Outcome: Death, maybe drug

21/09/2004

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective		The drug was ineffective - the patient committed suicide by jumping.	
Completed suicide			

Medicine Details:

ALPRAZOLAM (Other drug)	Reason:
2.0 Gram	
Batch:	Started: Stopped:
STILNOX (Other drug)	Reason:
10.0 Milligram	
Batch:	Started: Stopped:
AVANZA (Other drug)	Reason:
60.0 Milligram	
Batch:	Started: Stopped:
CHLORPROMAZINE HYDROCHLORIDE (Suspected)	Reason:
1.0 Dose Unspecified 1 time	
Batch:	Started: 20/09/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

She was taking ongoing Avanza, Zanax and Stilnox.
Report 201541 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 201542

Seq: 1

Gender: F

Reported: 08/10/2004

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date: 21/09/2004

DOB: 16/10/1946

Outcome: Death, maybe drug

21/09/2004

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)

Reason:

15.0 Milligram

Daily

Batch:

Started: 20/09/2004

Stopped:

0

Laboratory Investigations:

Additional Information:

She was taking ongoing Avanza, Zanax and Stilnox.
Report 201541 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 201612

Seq: 1

Gender: M

Reported: 11/10/2004

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 02/08/2004

DOB: 24/05/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Patient had a routine full blood evaluation and it was discovered he had decreased platelet levels.	

Medicine Details:

Medication Details:			
BENZTROPINE MESYLATE (Other drug)		Reason:	Unspecified psychosis
Batch:	Started:	Stopped:	0
FLUPHENAZINE DECANOATE (Other drug)		Reason:	Unspecified psychosis
Batch:	Started:	Stopped:	0
CHLORPROMAZINE HYDROCHLORIDE (Other drug)		Reason:	Unspecified psychosis
Batch:	Started:	Stopped:	0
Benzodiazepine NOS (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/10/2004	Platelets		16/08/2004	60	Platelet count in 1993 was 253 E3/L.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 201612

Seq: 1

Gender: M

Reported: 11/10/2004

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 02/08/2004

DOB: 24/05/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)

Reason: Unspecified schizophrenia

Tablet

5.0 Milligram

Daily

Oral

Batch:

Started: 30/07/2004

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 201692

Seq: 1

Gender: U

Reported: 13/10/2004

Weight: 80.00

Hospitalisation:

Age: 32

Onset Date: 02/10/2004

DOB: 17/01/1972

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Jaw disorder	Required Visit to Doctor	Patient developed jaw clenching/buccal dystonia.	Given Cogentin IM 2mg, then oral Cogentin 2mg bd.
Dystonia	Required Visit to Doctor		
Extrapyramidal disorder	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	20.0 Milligram	Daily	Oral
Batch:	Started: 15/09/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202017
Reported: 26/10/2004

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 10/09/2004
Outcome: Unknown

Age: 17
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polydactyly		On 10 September 2004 the mother vaginally delivered a full term infant at approximately 40 weeks gestation. The infant was born with an extra digit. There is no corrective treatment planned and the infant is otherwise healthy. The mother is healthy and had no delivery complications.	

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
Batch:	Started: Oral Stopped:
CANNABIS PREPARATION (Suspected)	Reason:
Batch:	Started: Stopped:
AMISULPRIDE (Suspected)	Reason:
Batch:	Started: Oral Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202020

Seq: 1

Gender: M

Reported: 26/10/2004

Weight: 132.00

Hospitalisation:

Onset Date: 21/02/2004

Age: 14

DOB: 25/04/1989

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Increased appetite	Required Visit to Doctor	The patient developed an increase in appetite and rapid weight gain of 20-25 kg over a 6 week period leading to severe disfiguring stretch marks over chest, upper back, abdomen and upper arms with skin breakdown in axillary region. The weight gain ceased with cessation of Olanzapine.	Vitamin E cream
Weight increased	Required Visit to Doctor		

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)		Reason:	
Tablet	20.0 Milligram		Oral
Batch:	Started: 01/11/2002	Stopped:	
SODIUM VALPROATE (Other drug)		Reason:	
Tablet	700.0 Milligram		Oral
Batch:	Started: 25/05/2003	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 21/02/2004	Stopped: 19/05/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202217

Seq: 1

Gender: M

Reported: 01/11/2004

Weight: 0.00

Hospitalisation:

Age: 35

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Inappropriate antidiuretic hormone		Patient experienced syndrome of inappropriate antidiuretic hormone secretion and bone marrow suppression.	
Bone marrow failure			

Medicine Details:

ZYPREXA (Suspected)	Reason:	Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202221 **Seq:** 1 **Gender:** M
Reported: 01/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 65
Onset Date: 15/10/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Coordination abnormal	Caused or prolonged inpatient hospitalisation	Patient experienced ataxia.	

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:
Batch:	Started:	Stopped:
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202256
Reported: 03/11/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 07/09/2004
Outcome: Unknown

Age: 61
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness		Patient complained of dizziness (postural?) in rehabilitation gym with physiotherapy.	Ciprofloxacin and Olanzapine ceased. Patient monitored.
Orthostatic hypotension			

Medicine Details:

CIPROFLOXACIN (Interaction)		Reason: Otr&nos infec¶sit diseases
	1.0 Gram	Daily Oral
Batch:	Started: 12/08/2004	Stopped: 07/09/2004 0
OLANZAPINE (Interaction)		Reason: Behavior disorders of childhod
Tablet	10.0 Milligram	Daily Oral
Batch:	Started: 06/07/2004	Stopped: 07/09/2004 0
CEPHALEXIN (Other drug)		Reason:
	2.0 Gram	Oral
Batch:	Started: 06/07/2004	Stopped: 07/09/2004
SPIRONOLACTONE (Other drug)		Reason:
Tablet	50.0 Milligram	Oral
Batch:	Started: 06/07/2004	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: CVA whilst undergoing CABG. Significant anxiety attacks whilst on 6B - olanzapine started by psych team. Previously heavy smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202256

Seq: 1

Gender: M

Reported: 03/11/2004

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 07/09/2004

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

FRUSEMIDE (Other drug)		Reason:	
	20.0 Milligram		Oral
Batch:	Started: 06/07/2004	Stopped:	
CITALOPRAM HYDROBROMIDE (Other drug)		Reason:	
Tablet	20.0 Milligram		Oral
Batch:	Started: 06/07/2004	Stopped:	
OXYCODONE HYDROCHLORIDE (Other drug)		Reason:	
	15.0 Milligram		Oral
Batch:	Started: 07/08/2004	Stopped:	
PARACETAMOL (Other drug)		Reason:	
	4.0 Gram		Oral
Batch:	Started: 06/07/2004	Stopped:	

Laboratory Investigations:

Additional Information:

History: CVA whilst undergoing CABG. Significant anxiety attacks whilst on 6B - olanzapine started by psych team. Previously heavy smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202256
Reported: 03/11/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 07/09/2004
Outcome: Unknown

Age: 61
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

SALBUTAMOL (Other drug)		Reason:
Inhalation	5.0 Milligram	Inhalation
Batch:	Started:	Stopped:
IPRATROPIUM BROMIDE (Other drug)		Reason:
Inhalation	250.0 Milligram	Inhalation
Batch:	Started: 06/07/2004	Stopped:
HEPARIN SALINE (Other drug)		Reason:
	300.0 Milligram	Oral
Batch:	Started: 06/07/2004	Stopped:
DIAZEPAM (Other drug)		Reason: Anxiety neurosis
	2.0 Milligram	As necessary
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

History: CVA whilst undergoing CABG. Significant anxiety attacks whilst on 6B - olanzapine started by psych team. Previously heavy smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202256

Seq: 1

Gender: M

Reported: 03/11/2004

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 07/09/2004

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

RAMIPRIL (Other drug)

Reason:

2.0 Milligram

Daily

Oral

Batch:

Started: 06/07/2004

Stopped:

0

Laboratory Investigations:

Additional Information:

History: CVA whilst undergoing CABG. Significant anxiety attacks whilst on 6B - olanzapine started by psych team. Previously heavy smoker.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202384

Seq: 1

Gender: F

Reported: 09/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase increased	Severe	Patient experienced gamma-glutamyltransferase increased, blood alkaline phosphates increased, alanine aminotransferase increased, severe nausea and vomiting lasting three weeks, drug toxicity, weight increased and drug concentration increased.	
Alanine aminotransferase increased	Severe		
Blood alkaline phosphatase increased	Severe		
Drug toxicity	Severe		
Nausea	Severe		
Vomiting	Severe		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2004	Serum drug level				Olanzapine 144 - above normal range. Olanzapine 123 - above normal range.

Additional Information:

Patient history: Schizophrenia, hepatitis B positive, hepatitis C positive, opiate abuse and alcohol abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202384

Seq: 1

Gender: F

Reported: 09/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Severe		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Patient history: Schizophrenia, heaptitis B positive, hepatitis C positive, opiate abuse and alcohol abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202412

Seq: 1

Gender: M

Reported: 09/11/2004

Weight: 100.00

Hospitalisation:

Onset Date: 25/10/2004

Age: 56

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea	Required Visit to Doctor	When patient lies down to sleep at night even though he is on a C PAP machine he wakes up unable to breath. Is also suffering severe constipation.	
Constipation	Required Visit to Doctor		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 01/04/2004	Stopped:	
LAMICTAL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 30/09/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202660

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient had suicidal ideation and was violent.	Discharged on Venlafaxine 225mg.
Aggression			

Medicine Details:

EFEXOR (Suspected)	Reason:	Oral
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202661

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 63

Onset Date:

DOB: 19/08/1941

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ALCOHOL (Suspected)		Reason:	
Oral Liquid		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202666

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient had suicidal ideation and was violent.	
Aggression			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
LOVAN (Suspected)		Reason:	
	40.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202685

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 66

Onset Date:

DOB: 24/12/1937

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

EFEXOR (Suspected)		Reason:	
	275.0 Milligram		Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202690

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 28/07/1970

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation and suicide attempt.	
Suicide attempt			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
	75.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202694

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

BRUFEN (Suspected)		Reason:	
Batch:	Started:	Stopped: Oral	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202722

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

LUVOX (Suspected)		Reason:	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202730

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZOLOFT (Suspected)		Reason:	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	9.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202735

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 19/09/1976

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation, suicide attempt and violence.	
Aggression			
Suicide attempt			

Medicine Details:

CIPRAMIL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202736

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date:

DOB: 09/08/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Patient became violent.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202741

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 12

Onset Date:

DOB: 20/12/1991

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Patient prone to violence.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202744

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 20/09/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose		Patient overdosed.	Zyprexa 5mg nocte and Cipramil 40mg. Both restarted.

Medicine Details:

CIPRAMIL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202746

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date:

DOB: 05/09/1961

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety		Patient suffered anxiety, was depressed and had suicidal ideation.	
Depression			
Suicidal ideation			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Oral	
Batch:	Started:	Stopped:	
EFEXOR (Suspected)		Reason:	
	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202749

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mania		Patient became manic, had suicidal ideation, was violent, had angry violent outbursts and akathisia.	Discharged on Fluvoxamine 200mg and Olanzapine 200mg or 5mg nocte.
Aggression			
Akathisia			
Suicidal ideation			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202761

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Onset Date: 04/08/2003

Age: 62

DOB: 16/08/1940

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

XANAX (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
EFEXOR (Suspected)		Reason:	
Batch:	Started:	Stopped:	Oral
Benzodiazepine NOS (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202764

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 22/10/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		Patient experienced akathisia.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
	38.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202768

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 48

Onset Date:

DOB: 04/08/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Patient stabbed self in stomach - suicide attempt.	

Medicine Details:

OLANZAPINE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202773

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date:

DOB: 23/06/1939

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient had mild hypomania and a death wish.	

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:
MIRTAZAPINE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
AROPAX (Suspected)	Reason:
	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202780

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 08/10/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Patient became abusive.	

Medicine Details:

SERTRALINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202781

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Patient became violent.	

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202782

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date:

DOB: 20/08/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation and suicide attempt.	
Suicide attempt			

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
EFEXOR (Suspected)		Reason:	
	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202802

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome		Suicidal ideation after Zyprexa ceased.	
Suicidal ideation			

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202806

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date:

DOB: 25/06/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional self-injury		Deliberate self harm.	

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202809

Seq: 1

Gender: U

Reported: 18/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		Patient developed akathisia and had a suicide attempt.	
Suicide attempt			

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection			
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
LUVOX (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202834

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicidal ideation and suicide attempt.	

Medicine Details:

MIRTAZAPINE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
EFEXOR (Suspected)	Reason:
	Oral
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202837

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Violent and suicide attempt.	
Suicide attempt			

Medicine Details:

ZYBAN SR (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202838

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicidal ideation and suicide attempt.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	200.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202839 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation	Caused or prolonged inpatient hospitalisation	Homicidal and suicidal ideation, violent and akathisia.	
Aggression	Caused or prolonged inpatient hospitalisation		
Akathisia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR (Suspected)		Reason:	
Batch:		Stopped: Oral	
Started:			
ZYPREXA (Suspected)		Reason:	
Batch:		Stopped:	
Started:			

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202839 **Seq:** 1 **Gender:** U
Reported: 19/11/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR (Suspected)		Reason:	
Batch:	Started:	Stopped: Oral	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202841

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation Akathisia		Homicidal ideation and akathisia.	

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202844

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Aggression		Suicidal ideation and violent.	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)		Reason:	
Capsule		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 202845

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Suicidal ideation.	

Medicine Details:

FLUVOXAMINE MALEATE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202847

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		Violent and suicidal ideation.	
Suicidal ideation			

Medicine Details:

ZYBAN SR (Interaction)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
ZYPREXA (Interaction)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202856

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Homicidal ideation Akathisia Overdose Suicidal ideation		Homicidal and suicidal ideation, akathisia and overdose.	

Medicine Details:

AROPAX (Suspected)		Reason:	
Batch:	Started:	Stopped: Oral	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking amphetamines.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 202860

Seq: 1

Gender: U

Reported: 19/11/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		Suicide attempt.	

Medicine Details:

AROPAX (Suspected)		Reason:	
Batch:	Started:	Stopped: Oral	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 203274 **Seq:** 1 **Gender:** M
Reported: 06/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder	Caused or prolonged inpatient hospitalisation	Patient began showing symptoms of obsessive compulsive disorder.	Electro convulsive therapy given. Lithium ceased.

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history of Bipolar disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 203294

Seq: 1

Gender: M

Reported: 06/12/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased		Olanzapine level in blood increased.	
Overdose		Patient died, drug toxicity.	
Drug ineffective			

Medicine Details:

ZYPREXA (Suspected)	Reason:
10.0 Milligram	Daily
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/12/2004	Serum drug level				Olanzapine levels were reported to have been 0.75mg/L.
06/12/2004	Serum drug level				Olanzapine levels were reported to have been 0.75mg/L and this was considered to be the cause of death.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 203375 **Seq:** 1 **Gender:** M
Reported: 08/12/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 08/11/2004 **DOB:** 16/11/1967
Outcome: Recovered 10/11/2004 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Stevens-Johnson syndrome	Caused or prolonged inpatient hospitalisation	Stevens Johnson syndrome and swelling of hands and feet.	Ibuprofen and Paracetamol.
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VENTOLIN (Other drug)	Reason:
Inhalation	Inhalation
Batch:	Started: Stopped:
FLIXOTIDE (Other drug)	Reason:
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason: Unspecified psychosis
Tablet	10.0 Milligram Daily Oral
Batch:	Started: 08/11/2004 Stopped: 09/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 203630
Reported: 17/12/2004

Seq: 1

Gender: F
Weight: 60.00
Age: 48
DOB: 28/01/1956
Causality: Causality possible

Hospitalisation:

Onset Date: 23/11/2004
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Excessive somnolence post general anaesthetic.	

Medicine Details:

PROPOFOL (Suspected) Injection Batch: Started: Stopped:	Reason: 1 time
MORPHINE SULPHATE (Suspected) Batch: Started: Stopped:	Reason: 1 time
SEVOFLURANE (Suspected) Inhalation Batch: Started: Stopped:	Reason: 1 time
VECURIUM BROMIDE (Suspected) Injection, powder for 6.0 Milligram Batch: Started: Stopped:	Reason: 1 time

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had 2 previous GAs with similar technique except no propofol (sevoflurane inductions) - normal recovery with dose GAs, but took 5 hours to regain consciousness this time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 203630
Reported: 17/12/2004

Seq: 1

Gender: F
Weight: 60.00
Age: 48
DOB: 28/01/1956
Causality: Causality possible

Hospitalisation:

Onset Date: 23/11/2004
Outcome: Recovered

Reaction Details:

Medicine Details:

DEXAMETHASONE (Suspected)		Reason:	
	8.0 Milligram	1 time	
Batch:	Started:	Stopped:	
NITROUS OXIDE (Suspected)		Reason:	
Inhalation	Litre	Per minute	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped: 22/11/2004	

Laboratory Investigations:

Additional Information:

Patient had 2 previous GAs with similar technique exopt no propofol (seroflurane inductions) - normal recovery with dose GAs, but took 5 hours to regain concioussness this time.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 203860 **Seq:** 1 **Gender:** F
Reported: 04/01/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 42Y
Onset Date: 02/07/2003 **DOB:**
Outcome: Death, maybe drug **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Prescribed overdose, drug toxicity, influenza like illness, sedation, found to be not breathing whilst travelling on a bus.	Zyprexa was decreased to 10mg daily.
Drug toxicity	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)		Reason:	
	5.0 Milligram		Oral
Batch:	Started:	Stopped:	
BENZTROPINE MESYLATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/01/2005	Other data				Cause of death was positional asphyxiation. Coroners report stated that there were toxic levels of Olanzapine in the patient's blood. Direct cause: Disease or condition directly leading to death: a) Olanzapine toxicity. Toxicology: Olanzapine (1.2mg/L), Diazepam (0.3mg/L), nordiazepam (0.8mg/L), benztropine (0.1mg/L) and sertraline (0.2mg/L) in blood. Quantitative procedures on blood showed diazepam ...

Additional Information:

The patient's medical history included behavioural disorder,intellectual disabilities, mild physical disability and non-communicative.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 203860

Seq: 1

Gender: F

Reported: 04/01/2005

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 42Y

Onset Date: 02/07/2003

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Medicine Details:

VALIUM (Other drug)	Reason:
5.0 Milligram	Oral
Batch:	Started: Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started: Stopped:
SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Tablet	30.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
					... (0.3mg/L, thr 0.05-2.0, txr 1.5-15, fr>5), nordiazepam (0.8mg/L, thr 0.1-2.0, txr 3-14, fr -), benziropine (0.1mg/L, thr 0.08-0.125, txr -, fr -0-7), sertraline (0.2mg/L, thr 0.1-0.3, txr -, fr -) and olanzapaine (1.2mg/L). No alcohol was detected in the submitted blood. (T031454).

Additional Information:

The patient's medical history included behavioural disorder,intellectual disabilities, mild physical disability and non-communicative.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204233
Reported: 14/01/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 30/11/2004

Age: 27

DOB: 08/08/1977

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Neutropenia.	Olanzapine discontinued.

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
300.0 Milligram	
Batch:	Started: Stopped:
RISPERDAL (Suspected)	Reason: Unspecified schizophrenia
5.0 Milligram	Daily Oral
Batch:	Started: 30/09/2004 Stopped:
OLANZAPINE (Suspected)	Reason: Unspecified schizophrenia
10.0 Milligram	Daily
Batch:	Started: 16/11/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2005	Neutrophils				1.67 and 1.45

Additional Information:

further information received and stated that the patient's condition has stabilized
Report 218010 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204253 **Seq:** 1 **Gender:** M
Reported: 14/01/2005 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: **DOB:** 11/09/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	The patient experienced cardiomyopathy requiring heart transplant urgently. Ejection fraction about 20%	ICU admission, Solian ceased. Antibiotics and possible heart transplant. Perindopril and carvedilol on discharge
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Cardiac failure	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Other drug)		Reason: Depression	
Capsule	300.0 Milligram	Oral	
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
	400.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 0
OLANZAPINE (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2005	Creatine				peaked at 343
14/01/2005	Other data	cardiac			dilated left ventricle of 78mm (normal 56mm)with severely depressed systolic function, estimated ejection fraction of <20% and mild mitral regurgitation.
14/01/2005	White blood cells				23.3 on day 3

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literature Report: Brakoulis V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal of Psychiatry. August 2005;39(8) 738



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204253 **Seq:** 1 **Gender:** M
Reported: 14/01/2005 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: **DOB:** 11/09/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Other drug)		Reason: Depression	
Capsule	300.0 Milligram	Oral	
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
	400.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 0
OLANZAPINE (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literature Report: Brakoulis V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal of Psychiatry. August 2005;39(8) 738



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204253 **Seq:** 1 **Gender:** M
Reported: 14/01/2005 **Weight:** 80.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: **DOB:** 11/09/1975
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EFEXOR-XR (Other drug)		Reason: Depression	
Capsule	300.0 Milligram	Oral	
Batch:	Started:	L TERM	Stopped:
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
	400.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 0
OLANZAPINE (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 0

Laboratory Investigations:

Additional Information:

Olanzapine withdrawn on week before admission. No previous exposure to amisulpride. PH of anxiety, panic disorder and alcohol abuse. Literature Report: Brakoulis V, banna E, Cohen P, geary G. Amisulpride and cardiomyopathy. Australian And New Zealand Journal of Psychiatry. August 2005;39(8) 738



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204256 **Seq:** 1 **Gender:** U
Reported: 14/01/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 69
Onset Date: 03/12/2004 **DOB:** 25/10/1935
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	The patient experienced myocarditis, increased troponin and ejection fraction decreased.	Olanzapine ceased, ACE inhibitors, supportive.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 22/11/2004	Stopped: 03/12/2004	
MIRTAZAPINE (Suspected)		Reason: Depression	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started: 15/01/2004	Stopped: 03/12/2004	
KEFLEX (Suspected)		Reason: Othr diseases of urinary tract	
	2.0 Milligram	Daily	Oral
Batch:	Started: 24/11/2004	Stopped: 07/12/2004	
HALOPERIDOL (Suspected)		Reason: Otr spec symp psychopathol nec	
	2.0 Milligram	Daily	
Batch:	Started: 22/11/2004	Stopped: 07/12/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/01/2005	Other data				LV impariment EF 30%
14/01/2005	Troponin				troponin rised 4.4

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 204455 **Seq:** 1 **Gender:** M
Reported: 22/01/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 22
Onset Date: 15/10/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Patient experienced a dystonic reaction which he explained to the doctor that it felt like and anxiety attack.	Antihistamine. SPECT ordered to scan for possible seizure. Zyprexa discontinued.
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0
VITAMIN NOS (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Depression	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204537

Seq: 1

Gender: F

Reported: 24/01/2005

Weight: 61.70

Hospitalisation:

Age: 26

Onset Date:

DOB: 15/10/1978

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		Extrapyramidal reaction with right tremor right lower limb and increased tone with rigidity.	
Hypertonia			
Muscle rigidity			
Tremor			

Medicine Details:

FOLIC ACID (Other drug)	Reason:
5.0 Milligram	
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
5.0 Milligram Daily	
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204628

Seq: 1

Gender: M

Reported: 25/01/2005

Weight: 67.40

Hospitalisation:

Age: 30

Onset Date: 18/10/2004

DOB: 27/11/1973

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Leukocytosis		The patient experienced leucocytosis.	Ceased Lithium.

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)		Reason: Unspecified psychosis	
Injection	40.0 Milligram	Yearly	
Batch:	Started: 20/08/2004	S TERM	Stopped:
LORAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 08/04/2004	S TERM	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	20.0 Milligram	Daily	Oral
Batch:	Started: 10/04/2004	S TERM	Stopped: 28/12/2004
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet	750.0 Milligram	Daily	Oral
Batch:	Started: 09/04/2004	S TERM	Stopped: 25/12/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/01/2005	Other data				13/12/2004 - Neutrophils, lymphocytes and basophils elevated.
25/01/2005	White blood cells		18/10/2004	12.7 x 10 ⁹	
25/01/2005	White blood cells		13/12/2004	13.5 x 10 ⁹	
25/01/2005	White blood cells		03/01/2005	11.6 x 10 ⁹	

Additional Information:

Patient has been exposed previously.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 204803
Reported: 01/02/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 04/08/2004

Age: 75

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness		Patient found unconscious at home after being discharged from hospital on Monday 02/08/04. Patient bradycardia, arrived in A&E alert but confused.	Ceased Aricept - possible problem with medication times. Commenced Levetiracetam 500mg twice daily.
Bradycardia			
Confusional state			

Medicine Details:

TEMAZEPAM (Other drug)		Reason: Specific disorders of sleep
Tablet	20.0 Milligram	Oral
Batch:	Started:	Stopped:
COLOXYL WITH SENNA (Other drug)		Reason: Constipation
Tablet	3.0 Dose Unspecified	Oral
Batch:	Started:	Stopped:
ARICEPT (Suspected)		Reason: Unspecified psychosis
Tablet	5.0 Milligram Daily	Oral
Batch:	Started:	Stopped: 04/08/2004 less than 1 wk
OLANZAPINE (Suspected)		Reason: Hallucinations
Tablet	10.0 Milligram Daily	Oral
Batch:	Started: S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has diffuse Lewy body disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204803

Seq: 1

Gender: M

Reported: 01/02/2005

Weight: 0.00

Hospitalisation:

Age: 75

Onset Date: 04/08/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

MADOPAR (Suspected)

Reason: Paralysis agitans

Tablet

250.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

Patient has diffuse Lewy body disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 204818 **Seq:** 1 **Gender:** M
Reported: 02/02/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: 12/08/2004 **DOB:** 18/11/1950
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus bradycardia	Caused or prolonged inpatient hospitalisation	Sinus bradycardia and intermittent sinus arrest.	Cessation of suspected offending agents.
Sinus arrest	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZE (Other drug)		Reason:	
	10.0 Milligram		
Batch:	Started: 29/07/2004	Stopped:	
DIAZEPAM (Other drug)		Reason:	
		Oral	
Batch:	Started: 29/07/2004	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 28/07/2004	Stopped: 11/08/2004	
SOLIAN (Suspected)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped: 20/08/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 205125 **Seq:** 1 **Gender:** M
Reported: 09/02/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 84
Onset Date: 25/11/2004 **DOB:**
Outcome: Recovered 06/01/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Patient developed neuroleptic malignant syndrome.	Haloperidol and Olanzapine ceased.

Medicine Details:

HALOPERIDOL (Interaction)		Reason: Otr spec symp psychopathol nec	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 20/11/2004	Stopped: 21/11/2004	
OLANZAPINE (Interaction)		Reason: Otr spec symp psychopathol nec	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 22/11/2004	Stopped: 25/11/2004	
AMPICILLIN (Other drug)		Reason:	
Injection	1.0 Gram		Intravenous
Batch:	Started: 19/11/2004	Stopped: 20/11/2004	
OXAZEPAM (Other drug)		Reason:	
Tablet	8.0 Milligram		Oral
Batch:	Started: 20/11/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/02/2005	Creatine		25/11/2004	2973	CKMB=27

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 205334

Seq: 1

Gender: F

Reported: 16/02/2005

Weight: 42.00

Hospitalisation:

Age: 60

Onset Date: 20/03/2004

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Blood pressure 70/40 on the 22/03/04.	Required medical attention.

Medicine Details:

THYROXINE SODIUM (Other drug)	Reason: Myxedema
175.0 Microgram	
Batch:	Started: Stopped:
MYADEC (Other drug)	Reason:
1.0 Dose Unspecified	
Batch:	Started: Stopped:
MOVICOL (Other drug)	Reason: Constipation
1.0 Dose Unspecified Daily	
Batch:	Started: Stopped:
DOXYCYCLINE HYDROCHLORIDE (Suspected)	Reason: Pneumonia,unspecified
Tablet 100.0 Milligram Daily Oral	
Batch:	Started: 20/03/2004 Stopped: 22/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 205334
Reported: 16/02/2005

Seq: 1

Gender: F
Weight: 42.00

Hospitalisation:

Onset Date: 20/03/2004
Outcome: Recovered

Age: 60
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

EPILIM (Suspected)		Reason:	
Oral Liquid, Syrup	2.0 Gram	Daily	Oral
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 22/03/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 205643 **Seq:** 1 **Gender:** M
Reported: 01/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced serotonin syndrome, confusional state, memory impairment, speech disorder, tremor, hypertidrosis, myoclonus, anxiety disorder, somatic hallucination and disorientation.	Fluoxetine ceased. Recommended Fluoxetine 20mg/daily.
Anxiety	Caused or prolonged inpatient hospitalisation		
Confusional state	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)		Reason: Depression	
Capsule	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason: Depression	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 205643 **Seq:** 1 **Gender:** M
Reported: 01/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Disorientation	Caused or prolonged inpatient hospitalisation		
Hallucination	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)		Reason: Depression
Capsule	80.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
OLANZAPINE (Interaction)		Reason: Depression
Tablet	2.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
DIAZEPAM (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 205643 **Seq:** 1 **Gender:** M
Reported: 01/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Memory impairment	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		
Speech disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)		Reason: Depression	
Capsule	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason: Depression	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 205643 **Seq:** 1 **Gender:** M
Reported: 01/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 53
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Interaction)		Reason: Depression	
Capsule	80.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Interaction)		Reason: Depression	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Literature report: World J Biol Psychiatry (2004) 5, 114-115: Serotonin Syndrome Associated with Fluoxetine and Olanzapine, Prem Chopra, Chee Ng, Isaac Schweltzer. Patient received a high dose of Fluoxetine previously with no adverse effects, the patient only developed serotonin syndrome after the addition of Olanzapine for three weeks.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 205906

Seq: 1

Gender: M

Reported: 10/03/2005

Weight: 0.00

Hospitalisation:

Onset Date: 17/02/2005

Age: 29

DOB: 06/12/1975

Outcome: Recovered

18/02/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chest pain		The patient experienced chest pain and T wave inversion V1-6.	
Electrocardiogram T wave inversio			

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:
Batch:	Started:	Stopped:
ASPIRIN (Other drug)		Reason:
Batch:	Started:	Stopped:
ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (Other drug)		Reason:
Batch:	Started:	Stopped:
Bisoprolol Fumarate (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
10/03/2005	Echocardiogram				Post recovery echocardiogram - Normal.
10/03/2005	Troponin				Normal.

Additional Information:

Patient has a history of cardiomyopathy to Clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 205906

Seq: 1

Gender: M

Reported: 10/03/2005

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date: 17/02/2005

DOB: 06/12/1975

Outcome: Recovered

18/02/2005

Causality: Causality possible

Reaction Details:

Medicine Details:

PERINDOPRIL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason:	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 17/02/2005	
OLANZAPINE (Suspected)		Reason:	
	30.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Patient has a history of cardiomyopathy to Clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206118 **Seq:** 1 **Gender:** U
Reported: 16/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 82Y
Onset Date: 16/02/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia	Caused or prolonged inpatient hospitalisation	Patient admitted bradycardic with atrial fibrillation, hypothermic, pin-point pupils and unresponsive with brief respiratory arrest.	
Atrial fibrillation	Caused or prolonged inpatient hospitalisation		
Hypothermia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AMARYL (Other drug)		Reason:	
4.0 Milligram			
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	
100.0 Milligram			
Batch:	Started:	Stopped:	
LIPITOR (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CHLORVESCENT (Other drug)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Recent change in dose. Zyprexa 2.5mg n 12/01/05. Admitted on 10mg d 16/02/05.
History - NIDDM, AF, MI (15 years ago) HT and dementia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206118 **Seq:** 1 **Gender:** U
Reported: 16/03/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 82Y
Onset Date: 16/02/2005 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Miosis	Caused or prolonged inpatient hospitalisation		
Respiratory arrest	Caused or prolonged inpatient hospitalisation		
Unresponsive to stimuli	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FRUSEMIDE (Other drug)	Reason:
Batch:	Started: Stopped:
PANAMAX (Other drug)	Reason:
Batch:	Started: Stopped:
KEFLEX (Other drug)	Reason:
Batch:	Started: Stopped:
FLUCLOXACILLIN SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Recent change in dose. Zyprexa 2.5mg n 12/01/05. Admitted on 10mg d 16/02/05.
History - NIDDM, AF, MI (15 years ago) HT and dementia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206118 **Seq:** 1

Reported: 16/03/2005

Hospitalisation: Admitted to hospital

Onset Date: 16/02/2005

Outcome: Not yet recovered

Gender: U

Weight: 0.00

Age: 82Y

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

PROTAPHANE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
DILATREND (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
LANOXIN PG (Suspected)		Reason:	
Tablet	62.0 Microgram	Daily	Oral
Batch:	Started:	Stopped:	
NEULACTIL (Suspected)		Reason:	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Recent change in dose. Zyprexa 2.5mg n 12/01/05. Admitted on 10mg d 16/02/05.
History - NIDDM, AF, MI (15 years ago) HT and dementia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206118 **Seq:** 1

Reported: 16/03/2005

Hospitalisation: Admitted to hospital

Onset Date: 16/02/2005

Outcome: Not yet recovered

Gender: U

Weight: 0.00

Age: 82Y

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

Zyprexa Zydis (Suspected)

Reason:

Wafer

10.0 Milligram

Daily

Oral

Batch:

Started:

Stopped: 07/02/2005

Laboratory Investigations:

Additional Information:

Recent change in dose. Zyprexa 2.5mg n 12/01/05. Admitted on 10mg d 16/02/05.
History - NIDDM, AF, MI (15 years ago) HT and dementia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 206159
Reported: 17/03/2005

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 05/09/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood prolactin increased		The patient's prolactin levels increased.	Treated with Cabergoline. All medications ceased except Methadone.

Medicine Details:

METHADONE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Change in voice	
		Oral	
Batch:	Started: 01/11/2004	Stopped: 17/12/2005	0
SODIUM VALPROATE (Suspected)		Reason:	
		Oral	
Batch:	Started:	Stopped:	0
AVANZA (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/03/2005	Prolactin		17/11/2004	8034	
17/03/2005	Prolactin		20/12/2004	112	

Additional Information:

It is unknown how long the patient was receiving Olanzapine before she experienced elevated prolactin levels. All medications were ceased except Methadone and the prolactine levels returned to normal.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206159

Seq: 1

Gender: F

Reported: 17/03/2005

Weight: 0.00

Hospitalisation:

Age: 24

Onset Date:

DOB: 05/09/1980

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

DIAZEPAM (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
TEMAZEPAM (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
CAMPRAL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Additional Information:

It is unknown how long the patient was receiving Olanzapine before she experienced elevated prolactin levels. All medications were ceased except Methadone and the prolactine levels returned to normal.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206280

Seq: 1

Gender: F

Reported: 28/03/2005

Weight: 54.00

Hospitalisation:

Age: 15

Onset Date: 09/01/2005

DOB: 21/06/1989

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening	Attempt to hang herself with television cord from curtain rail in hospital bedroom. Nurse said she found her at the last moment.	
Drug ineffective	Life threatening		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PROZAC (Suspected)		Reason:	
Tablet	Milligram	Daily	Oral
Batch:	Started: 16/12/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 206282

Seq: 1

Gender: F

Reported: 28/03/2005

Weight: 54.00

Hospitalisation:

Age: 15

Onset Date: 20/12/2004

DOB: 21/06/1989

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening	Suicide attempt. Ingested 40 Panadol tablets. Also frequent self harming	Charcoal and drip of drug to break down the paracetamol.
Drug ineffective	Life threatening		
Self injurious behaviour	Life threatening		

Medicine Details:

PANADOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PANADEINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
PROZAC (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 16/12/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206283

Seq: 1

Gender: F

Reported: 28/03/2005

Weight: 54.00

Hospitalisation:

Onset Date: 23/03/2005

Age: 15

DOB: 21/06/1989

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening	Attempted suicide by ingestion of 80 Panadol, 20 Panadeine, 7 Olanzapine (Zyprexa.)	Charcoal, drips of various antidotes including one for breaking down paracetamol, ventilator, all monitors, intensive care for 20 hours. She is now having constant convulsions. These started on 26 March 2005 and are continuing. On 26 march they were of long duration and with only breaks of 10 or 20 minutes. On 27 March they were of various duration and sometimes an hour or ...

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PANADOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PANADEINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PROZAC (Suspected)		Reason:	
Tablet	Milligram	Daily	Oral
Batch:	Started: 16/12/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206283

Seq: 1

Gender: F

Reported: 28/03/2005

Weight: 54.00

Hospitalisation:

Age: 15

Onset Date: 23/03/2005

DOB: 21/06/1989

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Life threatening		... two apart. Today she has already had some fits today. The hospital cannot work out the cause.
Drug ineffective	Life threatening		

Medicine Details:

Medicine Details:			
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PANADOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PANADEINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
PROZAC (Suspected)		Reason:	
Tablet	Milligram	Daily	Oral
Batch:	Started: 16/12/2004	Stopped:	

Laboratory Investigations:

Additional Information:

One patient with ADRs 206280, 206281, 206282 206283. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206455 **Seq:** 1 **Gender:** F
Reported: 01/04/2005 **Weight:** 75.00
Hospitalisation: Admitted to hospital **Age:** 56
Onset Date: 08/03/2005 **DOB:** 01/02/1949
Outcome: Recovered 15/03/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash macular	Caused or prolonged inpatient hospitalisation	Patient developed macular rashes, generalised eruptive rashes over body/limbs/groin/lower abdomen area/chest/armpit/arm/thighs.	Phenergan 20mg tds.

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Tablet	5.0 Milligram		Oral
Batch:	Started: 03/03/2005	Stopped: 06/03/2005	
SODIUM VALPROATE (Suspected)		Reason:	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 01/03/2005	Stopped: 08/03/2005	
OLANZAPINE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 07/03/2005	Stopped: 08/03/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206466
Reported: 01/04/2005

Seq: 1

Gender: F
Weight: 104.00

Hospitalisation:

Onset Date: 26/02/2005

Age: 46Y

Outcome: Recovered

07/03/2005

DOB:

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arthralgia Food craving Vision blurred		Patient experienced joints pains, food cravings and blurred vision.	Zyprexa ceased.

Medicine Details:

TOFRANIL (Other drug)	Reason:	Depression
Batch:	Started:	Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason:	
Batch:	Started:	Stopped:
Symbicort Turbuhaler (Other drug)	Reason:	
Batch:	Started:	Stopped:
CALTRATE (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had had same reactions while previously on Zyprexa June 2004-> Dec 30th 2004. was symptom free until re-started it late Feb.
Lowered dose then ceased Zyprexa 5/03/05.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 206466

Seq: 1

Gender: F

Reported: 01/04/2005

Weight: 104.00

Hospitalisation:

Age: 46Y

Onset Date: 26/02/2005

DOB:

Outcome: Recovered

07/03/2005

Causality: Causality certain

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)

Reason:

Tablet

5.0 Milligram

Daily

Oral

Batch:

Started: 24/02/2005

Stopped: 05/03/2005 0

Laboratory Investigations:

Additional Information:

Patient had had same reactions while previously on Zyprexa June 2004-> Dec 30th 2004. was symptom free until re-started it late Feb.
Lowered dose then ceased Zyprexa 5/03/05.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 206678
Reported: 05/04/2005

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date: 03/03/2005

Age: 53

DOB: 08/01/1952

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Alanine aminotransferase increase Aspartate aminotransferase increase Blood bilirubin increased Blood lactate dehydrogenase increase Fatigue Gamma-glutamyltransferase increase Influenza like illness Jaundice		During the first two weeks of the patient receiving Olanzapine she experienced elevated liver function tests and jaundice.	Olanzapine ceased.

Medicine Details:

LUVOX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Depression	
	5.0 Milligram	Daily	Oral
Batch:	Started: 22/02/2005	Stopped: 08/03/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/04/2005	ALT = SGPT				514 on 03/03/2005
05/04/2005	AST = SGOT				253 on 03/03/2005
05/04/2005	Bilirubin				27 on 03/03/2005
05/04/2005	GGT = SGGT =				414 on 03/03/2005
05/04/2005	LDH				477 on 03/03/2005

Additional Information:

Alanine aminotransferase value of approximately 500u/l. No normal values provided, but the psychiatrist commented that it was greater than ten times the expected value.
Patients medical history included depression, diabetes and a gall bladder problem.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 206888

Seq: 1

Gender: F

Reported: 11/04/2005

Weight: 0.00

Hospitalisation:

Age: 70

Onset Date:

DOB: 10/04/1935

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Incapacity/disability	After commencing Olanzapine the patient experienced abnormal movement of the torso and orobuccal region, described by her family as stiff and robotic. She was diagnosed with tardive dyskinesia.	Olanzapine ceased.

Medicine Details:

CELEBREX (Other drug)		Reason:	
Capsule	200.0 Milligram	Oral	
Batch:	Started:	Stopped:	
KLIOGEST (Other drug)		Reason:	
Tablet	2.0 Milligram	Oral	
Batch:	Started:	Stopped:	
TEMAZEPAM (Other drug)		Reason:	
	10.0 Milligram	Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Depression	
	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 08/02/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 207039

Seq: 1

Gender: M

Reported: 14/04/2005

Weight: 0.00

Hospitalisation:

Onset Date: 06/02/2005

Age: 58

DOB: 11/04/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		The patient developed a rash starting on the torso and spreading down the arms and legs. It was very red, blotchy and itchy.	Amiodarone ceased.
Pruritus			

Medicine Details:

RAMIPRIL (Other drug)	Reason:
Batch:	Started: Stopped:
SPIRONOLACTONE (Other drug)	Reason:
Batch:	Started: Stopped:
FRUSEMIDE (Other drug)	Reason:
Batch:	Started: Stopped:
CARVEDILOL HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 207033 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207039

Seq: 1

Gender: M

Reported: 14/04/2005

Weight: 0.00

Hospitalisation:

Age: 58

Onset Date: 06/02/2005

DOB: 11/04/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PRAVACHOL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
DIGOXIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
WARFARIN SODIUM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
AMIODARONE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 21/01/2005	Stopped: 07/02/2005	

Laboratory Investigations:

Additional Information:

Report 207033 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207039

Seq: 1

Gender: M

Reported: 14/04/2005

Weight: 0.00

Hospitalisation:

Age: 58

Onset Date: 06/02/2005

DOB: 11/04/1946

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)

Reason:

5.0 Milligram

Daily

Batch:

Started: 06/02/2005

Stopped:

Laboratory Investigations:

Additional Information:

Report 207033 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207223

Seq: 1

Gender: F

Reported: 19/04/2005

Weight: 75.00

Hospitalisation:

Age: 53

Onset Date: 27/02/2005

DOB: 08/01/1952

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient developed acute hepatic symptoms, flu-like illness, elevated LFT.	

Medicine Details:

FLUVOXAMINE MALEATE (Other drug)		Reason: Depression	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 23/02/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 207619
Reported: 05/05/2005

Seq: 1

Gender: U
Weight: 0.00
Age: 99u

Hospitalisation:

Onset Date: 22/11/2004
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia Anorexia Arthralgia Fatigue Headache Myalgia		Patient developed fever, tiredness, lethargy, joint pain, headache, anorexia and muscle aches.	Fluid resus and Bromocriptine given.

Medicine Details:

CLOZAPINE (Suspected)		Reason:	
Tablet			Oral
Batch:	Started: 17/11/2004	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	
ATORVASTATIN (Suspected)		Reason:	
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped: 23/11/2004	
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason:	
	20.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped: 23/11/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Nil muscle rigidity.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207619

Seq: 1

Gender: U

Reported: 05/05/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date: 22/11/2004

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

CELEBREX (Suspected)

Reason:

Capsule

20.0 Milligram

Daily

Oral

Batch:

Started:

S TERM

Stopped:

Laboratory Investigations:

Additional Information:

Nil muscle rigidity.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207760

Seq: 1

Gender: M

Reported: 12/05/2005

Weight: 0.00

Hospitalisation:

Age: 28

Onset Date: 20/04/2005

DOB: 02/01/1977

Outcome: Recovered with sequelae

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetic ketoacidosis	Life threatening	Patient was admitted to ICU with diabetic ketoacidosis following a 3 week history of weight loss (10 kg), polyuria.	Fluid and electrolyte replacement. Insulin. Zyprexa and Seroquel ceased. Abilify commenced
Polyuria	Life threatening		
Weight decreased	Life threatening		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	20.0 Milligram	1 time	Oral
Batch:	Started: 01/04/2004	Stopped: 02/05/2005	
SEROQUEL (Suspected)		Reason:	
Tablet	400.0 Milligram	1 time	Oral
Batch:	Started: 01/04/2004	Stopped: 02/05/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/05/2005	Biochemistry				Hypokalemia, hyperglycaemia

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207829
Reported: 13/05/2005
Hospitalisation:
Onset Date: 20/07/1998
Outcome: Unknown

Seq: 1

Gender: M
Weight: 98.00
Age: 49Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation	The patient experienced cogwheeling, stiffness and extrapyramidal syndrome.	Given Bzotropine.
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Musculoskeletal stiffness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason: Unspecified schizophrenia	
	8.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 23/07/1998	
OLANZAPINE (Suspected)		Reason:	
	8.0 Milligram	Daily	
Batch:	Started:	Stopped: 20/07/1998	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Clinical trial RODOS WAVE I:RODOS.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207913
Reported: 17/05/2005

Seq: 1

Gender: F
Weight: 39.00

Hospitalisation:

Onset Date: 04/04/2005

Age: 62

DOB: 07/05/1942

Outcome: Recovered

12/04/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Life threatening	The patient developed agranulocytosis - her neutrophil count dropped to zero.	Neupogen given.

Medicine Details:

SERETIDE ACCUHALER NOS (Other drug)		Reason: Asthma
Batch:	Started:	Stopped:
ASPIRIN (Other drug)		Reason: Acute, ill-def cerebrovascular disease w/o hypert
	100.0 Milligram	Daily Oral
Batch:	Started:	Stopped:
MIRTAZAPINE (Suspected)		Reason: Depression
Tablet	30.0 Milligram	Daily Oral
Batch:	Started: 30/01/2005	Stopped: 04/04/2005
EFEXOR-XR (Suspected)		Reason: Depression
Capsule	150.0 Milligram	Daily Oral
Batch:	Started: 16/02/2005	Stopped: 04/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/05/2005	Bone marrow				Consistent with drug effect.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207913

Seq: 1

Gender: F

Reported: 17/05/2005

Weight: 39.00

Hospitalisation:

Age: 62

Onset Date: 04/04/2005

DOB: 07/05/1942

Outcome: Recovered

12/04/2005

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason: Depression	
	5.0 Milligram	Daily	
Batch:	Started: 22/02/2005	Stopped: 04/04/2005	
LOSEC (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started: L TERM	Stopped: 04/04/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 207940 **Seq:** 1 **Gender:** M
Reported: 17/05/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 78
Onset Date: 18/02/2005 **DOB:** 19/05/1926
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradycardia	Caused or prolonged inpatient hospitalisation	Patient experienced bradycardia, severe hypothermia, pin-point pupils and unresponsive in critical condition.	
Hypothermia	Caused or prolonged inpatient hospitalisation		
Miosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ASPIRIN (Other drug)	Reason:
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
RIVOTRIL (Other drug)	Reason:
Batch:	Started: Stopped:
DIPROSONE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: Dementia and multiple other medical problems.
Another patient admitted on 17.2.05 with same reaction.
Common factor could be starting or changed dose Zyprexa.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 207940 **Seq:** 1 **Gender:** M
Reported: 17/05/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 78
Onset Date: 18/02/2005 **DOB:** 19/05/1926
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Unresponsive to stimuli	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	2.5 Milligram	2 times	Oral
Batch:	Started: 16/02/2005	Stopped:	18/02/2005

Laboratory Investigations:

Additional Information:

Patient history: Dementia and multiple other medical problems.
Another patient admitted on 17.2.05 with same reaction.
Common factor could be starting or changed dose Zyprexa.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 207984

Seq: 1

Gender: F

Reported: 19/05/2005

Weight: 62.00

Hospitalisation:

Age: 24Y

Onset Date: 25/04/2005

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Face oedema		Patient experienced facial oedema.	Nil

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
5.0 Milligram	Daily
Oral	
Batch:	Started: 18/04/2005
	Stopped: 25/04/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208386 **Seq:** 1 **Gender:** F
Reported: 01/06/2005 **Weight:** 64.00
Hospitalisation: Admitted to hospital **Age:** 36
Onset Date: 01/10/2004 **DOB:** 13/11/1967
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis	Caused or prolonged inpatient hospitalisation	Severe drug-related hepatitis	Supportive
Jaundice	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	1 time	Oral
Batch:	Started: 01/06/2003	Stopped: 20/10/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/06/2005	Biochemistry				Bili: 590; ALP: 182; GGT: 69; AST: 1830; ALT: 1690; LDH: 500 LFT's normal 27/1/05.
01/06/2005	Liver biopsy				Liver biopsy showed zone 3 ballooning degeneration with giant cell transformation apoptotic bodies and portal and acinar infiltrates of lymphocytes and plasma cells.

Additional Information:

Liver Biopsy complicated by major bleeding requiring admission to ICU and laparotomy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208386

Seq: 1

Gender: F

Reported: 01/06/2005

Weight: 64.00

Hospitalisation: Admitted to hospital

Age: 36

Onset Date: 01/10/2004

DOB: 13/11/1967

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	1 time	Oral
Batch:	Started: 01/06/2003	Stopped: 20/10/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/06/2005	Other data				PT 27S (control 10s) initially - reversed with Vit K to 13s. HAV, HBV, HCV, EBV, CMV serology negative. Ultrasound showed no evidence of biliary obstruction.

Additional Information:

Liver Biopsy complicated by major bleeding requiring admission to ICU and laparotomy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208441

Seq: 1

Gender: F

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date:

DOB: 30/11/1979

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		The patient made a suicide attempt.	

Medicine Details:

CIPRAMIL (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
EFEXOR (Suspected)	Reason:
	Oral
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 208442 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208444

Seq: 1

Gender: F

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 32

Onset Date:

DOB: 24/08/1972

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression		The patient became violently aggressive, physically threatening and abusive.	Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208446

Seq: 1

Gender: F

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date:

DOB: 20/02/1985

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Influenza like illness		The patient continued to be suicidal on Zyprexa and made another attempt at self-harm. After it was stopped she had a 'flu-like' illness, which could have been influenza or Zyprexa withdrawal syndrome.	Zyprexa ceased.
Drug withdrawal syndrome			
Suicide attempt			

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 208445 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208452

Seq: 1

Gender: U

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date:

DOB: 18/07/1958

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		The patient experienced suicidal ideation and a suicidal act while taking a combination of Zyprexa, Lexapro and alcohol.	Zyprexa, Lexapro and alcohol ceased.
Suicide attempt			

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:
Lexapro (Suspected)	Reason:
Batch:	Started: Stopped: Oral
ALCOHOL (Suspected)	Reason:
Oral Liquid	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208458

Seq: 1

Gender: F

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 59

Onset Date:

DOB: 04/09/1945

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	The patient experienced suicidal ideation, suicide attempt and homicidal ideation - she attempted to kill her parents.	
Homicidal ideation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208460

Seq: 1

Gender: F

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 07/12/1974

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia Aggression Drug withdrawal syndrome Suicidal ideation		The patient voluntarily ceased all medications and within days she was in full akathisia, restless, obsessively suicidal and violent.	

Medicine Details:

THIAMINE (Other drug)	Reason:
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:
VALIUM (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208466
Reported: 03/06/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date:

DOB: 30/06/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient became restless, developed akathisia and was suicidal and homicidal. He experienced a suicide attempt - tried to drive into a tree. He was also agitated.	Failed to respond to ECT or tricycles. Given Olanzapine 10mg and Zuclopenthixol 300mg.
Agitation	Caused or prolonged inpatient hospitalisation		
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Suspected)		Reason:	
Batch:		Stopped:	
Started:		Oral	
OLANZAPINE (Suspected)		Reason:	
Batch:		Stopped:	
Started:			

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208468

Seq: 1

Gender: U

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 70Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt		The patient experienced a serious suicidal attempt after three months of akathisia - made serious, nearly lethal attempts, and developed deep vein thrombosis.	Withdrawal over prolonged period. Needed Warfarin.
Akathisia			
Deep vein thrombosis			

Medicine Details:

ZUCLOPENTHIXOL ACETATE (Suspected)		Reason:	
Injection	200.0 Milligram	Weekly	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	
FLUVOXAMINE MALEATE (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208476

Seq: 1

Gender: F

Reported: 03/06/2005

Weight: 0.00

Hospitalisation:

Age: 75Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral		Patient developed peripheral oedema and cardiac failure	Patient discontinued Olanzapine and started treatment with Amisulpride, patient's symptoms worsened and patient restarted treatment with Olanzapine.
Cardiac failure			

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis
Tablet	7.5 Milligram Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208607

Seq: 1

Gender: F

Reported: 09/06/2005

Weight: 0.00

Hospitalisation: Required a visit to the doctor

Age: 29Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orgasmic sensation decreased		The patient has been unable to orgasm since commencing Zyprexa.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Post stress disorder and on many medications.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208666
Reported: 10/06/2005

Seq: 1

Gender: F
Weight: 54.00

Hospitalisation:

Onset Date: 08/06/2005
Outcome: Recovered

Age: 15
DOB: 21/06/1989

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening	Suicide Attempt, strangling herself with the iPod cord in the bathroom of the hospital. Agitation, She ran around crying and banging her fists of the walls and windows begging to be let out...it lasted about 10 minutes before I could settle her...and they gave her extra Olanzapine then too. Withdrawal reaction, when Olanzapine is wearing off, they give her extra Olanzapine. Akathisia	Agitation, Withdrawal reaction, Akathisia -> given extra Olanzapine.
Akathisia	Life threatening		

Medicine Details:

OLANZAPINE (Suspected)					Reason:	
	10.0	Milligram	Daily	Oral		
Batch:	Started:		Stopped:			0
FLUOXETINE HYDROCHLORIDE (Suspected)					Reason:	
	20.0	Milligram	Daily	Oral		
Batch:	Started:		Stopped:			0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One patient with ADRs 206280, 206281, 206282, 206283, 208666. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208666

Seq: 1

Gender: F

Reported: 10/06/2005

Weight: 54.00

Hospitalisation:

Age: 15

Onset Date: 08/06/2005

DOB: 21/06/1989

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Life threatening		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason:	
	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Additional Information:

One patient with ADRs 206280, 206281, 206282, 206283, 208666. She takes Olanzapine to help her sleep. She is not psychotic (per reporter).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208671
Reported: 14/06/2005

Seq: 1

Gender: M

Weight: 60.00

Hospitalisation:

Age: 15

Onset Date:

DOB: 03/08/1989

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood triglycerides increased	Caused or prolonged inpatient hospitalisation	raised consecutive triglyceride levels whilst on olanzapine - date: 2 weeks post initiation and then 3 weeks post initiation	necessitated change of medication

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	12.5 Milligram	1 time	Oral
Batch:	Started: 23/05/2005	Stopped:	14/06/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/06/2005	Biochemistry				20/05/2005 triglyceride 0.8mmol/L; 2/6/2005 triglyceride 1.7mmol/L 9/6/05 triglyceride 3.8mmol/L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208713
Reported: 16/06/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 21/05/2005

Age: 29

DOB: 01/11/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swollen tongue		Patient experienced swollen tongue and difficulty speaking, shakey and trouble with co-ordination.	Treated with Cogentin 2mg oral 02/02/05 and 1mg 02/03/05..
Coordination abnormal			
Nervousness			
Speech disorder			

Medicine Details:

OMEPRAZOLE (Other drug)		Reason:	
	20.0 Milligram		
Batch:	Started: 19/05/2005	Stopped:	
CLOPIXOL-ACUPHASE (Suspected)		Reason:	
Injection	100.0 Milligram	Daily	Intramuscular
Batch:	Started: 20/05/2005	Stopped:	
QUETIAPINE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 20/05/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 21/05/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208837 **Seq:** 1 **Gender:** F
Reported: 21/06/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 37Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Necrobiosis lipoidica diabetorum		Patient developed Necrobiosis Lipoidica Diabeticorum on legs and fat necrosis.	
Fat necrosis			

Medicine Details:

VALIUM (Suspected)		Reason: Convulsions As necessary	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
	22.5 Milligram	Daily	
Batch:	Started:	L TERM	Stopped: 0
TEGRETOL (Suspected)		Reason: Convulsions	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DIABEX (Suspected)		Reason: Diabetes mellitus	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 15/05/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Family history: Grandmother developed type 1 diabetes in later years. Has had previous leg ulcer (from a tick bite) her blisters take a long time to heal. Seizures since 10 years of age.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208869

Seq: 1

Gender: F

Reported: 21/06/2005

Weight: 0.00

Hospitalisation:

Age: 41Y

Onset Date: 15/02/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase increase		Patient experienced increased gamma glutamyl transferase, alanine aminotransferase and alkaline phosphatase levels.	
Alanine aminotransferase increase			
Blood alkaline phosphatase increase			

Medicine Details:

ZYPREXA (Suspected)	Reason: Manic-depression psycho,manic
Tablet	10.0 Milligram
	Daily
	Oral
Batch:	Started: 15/12/2003
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	ALT = SGPT		15/06/2003	88 U/liter	Total 24
21/06/2005	ALT = SGPT		15/02/2004	229 U/liter	
21/06/2005	ALT = SGPT		15/01/2005	314 U/liter	
21/06/2005	ALT = SGPT		05/04/2005	273 U/liter	
21/06/2005	Bilirubin				
21/06/2005	GGT = SGGT =		15/06/2002	54 U/liter	
21/06/2005	GGT = SGGT =		15/06/2003	77 U/liter	

Additional Information:

History: Bipolar disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208869

Seq: 1

Gender: F

Reported: 21/06/2005

Weight: 0.00

Hospitalisation:

Age: 41Y

Onset Date: 15/02/2004

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)

Reason: Manic-depression psycho,manic

Tablet

10.0 Milligram

Daily

Oral

Batch:

Started: 15/12/2003

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
21/06/2005	GGT = SGGT =		15/01/2005	350 U/liter	
21/06/2005	GGT = SGGT =		15/02/2004	176 U/liter	
21/06/2005	GGT = SGGT =		05/04/2005	180 U/liter	
21/06/2005	Other data		15/02/2004	120 U/liter	Alkaline Phosphatase
21/06/2005	Other data		15/01/2005	133 U/liter	Alkaline Phosphatase
21/06/2005	Other data		05/05/2005	109 U/liter	Alkaline Phosphatase

Additional Information:

History: Bipolar disorder.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208945

Seq: 1

Gender: F

Reported: 22/06/2005

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 24/05/2005

DOB: 21/08/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aspartate aminotransferase increa	Caused or prolonged inpatient hospitalisation	Five days after starting Olanzapine treatment the patient experienced elevated aspartate aminotransferase, alanine aminotransferase and gamma glutamyl transferase levels.	Olanzapine ceased.
Alanine aminotransferase increase	Caused or prolonged inpatient hospitalisation		
Blood alkaline phosphatase increa	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Otr spec symp psychopathol nec
10.0 Milligram	Daily Oral
Batch:	Started: 19/05/2005 Stopped: 24/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/06/2005	ALT = SGPT		19/05/2005	20	
22/06/2005	ALT = SGPT		24/05/2005	305	
22/06/2005	AST = SGOT		19/05/2005	17	
22/06/2005	AST = SGOT		24/05/2005	205	
22/06/2005	GGT = SGGT =		19/05/2005	34	
22/06/2005	GGT = SGGT =		24/05/2005	76	
22/06/2005	SAP = ALP		19/05/2005	48	

Additional Information:

Dose was increased from 5mg per day at night to 10mg per day.
Thyroid irregularities (thyroid disorder NOS).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208945

Seq: 1

Gender: F

Reported: 22/06/2005

Weight: 0.00

Hospitalisation:

Age: 42

Onset Date: 24/05/2005

DOB: 21/08/1962

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase increa	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Otr spec symp psychopathol nec
10.0 Milligram	Daily Oral
Batch:	Started: 19/05/2005 Stopped: 24/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/06/2005	SAP = ALP		24/05/2005	78	

Additional Information:

Dose was increased from 5mg per day at night to 10mg per day.
Thyroid irregularities (thyroid disorder NOS).



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208978

Seq: 1

Gender: F

Reported: 23/06/2005

Weight: 55.00

Hospitalisation:

Age: 75Y

Onset Date: 20/05/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pain in extremity		The patient experienced aching legs, severe enough for her to refuse to take the drug.	Zyprexa Zydis ceased.

Medicine Details:

Zyprexa Zydis (Suspected)	Reason: Unspecified psychosis
Wafer	5.0 Milligram Daily Oral
Batch:	Started: 26/04/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 208989
Reported: 23/06/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 24/03/2005

Age: 65

DOB: 18/12/1939

Outcome: Recovered

24/03/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	The patient experienced a seizure which lasted for 25 minutes. There was no history of epilepsy.	IV Diazepam.

Medicine Details:

CELEBREX (Other drug)		Reason:	Osteoarthritis
Batch:	Started:	Stopped:	
HYDROCHLOROTHIAZIDE (Other drug)		Reason:	Essential benign hypertension
Batch:	Started:	Stopped:	
CANDESARTAN CILEXETIL (Other drug)		Reason:	Essential benign hypertension
Batch:	Started:	Stopped:	
Risperdal Consta (Suspected)		Reason:	Unspecified psychosis
Injection	1.0 Dose Unspecified	1 time	Intramuscular
Batch:	Started: 10/03/2005		Stopped: 10/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: thiazide - hyponatraemia



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 208989

Seq: 1

Gender: F

Reported: 23/06/2005

Weight: 0.00

Hospitalisation:

Age: 65

Onset Date: 24/03/2005

DOB: 18/12/1939

Outcome: Recovered

24/03/2005

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	Oral
Batch:	Started: 17/03/2005	Stopped: 24/03/2005	
RISPERDAL (Suspected)		Reason: Unspecified psychosis	
	1.0 Milligram	Daily	Oral
Batch:	Started: 18/02/2005	Stopped: 17/03/2005	

Laboratory Investigations:

Additional Information:

Patient history: thiazide - hyponatraemia



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 209083
Reported: 24/06/2005

Seq: 1

Gender: F
Weight: 60.00

Hospitalisation:

Onset Date: 15/02/2005
Outcome: Recovered

Age: 47
DOB: 23/11/1957
Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Condition aggravated		The patient experienced worsening of rheumatoid arthritis producing frank joint effusion in one knee.	Reducing dose.

Medicine Details:

EFEXOR-XR (Other drug)		Reason:	
	2.5 Gram		
Batch:	Started:	L TERM	Stopped:
TEMAZEPAM (Other drug)		Reason:	
Capsule	20.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
SODIUM VALPROATE (Other drug)		Reason:	
	1.0 Gram	Daily	
Batch:	Started:	S TERM	Stopped:
ZYPREXA (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

This seemed to be an Olanzapine affect since it improved with dose reduction and increase with rechallenge at higher dose.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 209302 **Seq:** 1 **Gender:** F
Reported: 30/06/2005 **Weight:** 90.00
Hospitalisation: Required a visit to the doctor **Age:** 34
Onset Date: 06/04/2005 **DOB:** 26/07/1970
Outcome: Recovered 07/04/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Transient ischaemic attack	Caused or prolonged inpatient hospitalisation	Patient experienced transient ischaemic attack.	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	
PROTHIADEN (Suspected)		Reason: Depression	
	225.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 209424
Reported: 04/07/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 25Y

Onset Date:

DOB:

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asthma	Death	Within a few minutes of IM Olanzapine administration the patient died. His agitated state appears to have occurred simultaneously with acute asthmatic symptoms and dyspnoea, described by the reporting psychiatrist as status asthmaticus, with death following shortly thereafter.	
Death	Death		

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:	Oral
Batch:	Started:	Stopped:
ZYPREXA (Suspected)	Reason:	Unspecified schizophrenia Oral
Batch:	Started:	Stopped: 0
CLONAZEPAM (Suspected)	Reason:	Otr spec symp psychopathol nec
2.0 Milligram	1 time	
Batch:	Started:	Stopped:
Zyprexa IM (Suspected)	Reason:	Otr spec symp psychopathol nec
Injection	10.0 Milligram	Daily Intramuscular
Batch:	Started:	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 209449 **Seq:** 1 **Gender:** M
Reported: 05/07/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 30Y
Onset Date: 12/09/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation	The patient developed mixed liver function test abnormality.	Withdrawal of Cephazolin.

Medicine Details:

ASPIRIN (Other drug)	Reason:
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:
HEPARIN SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:
MAXOLON (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/07/2005	ALT = SGPT				ALT 212.
05/07/2005	Bilirubin				Bili 30.
05/07/2005	SAP = ALP				ALP 152.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 209449

Seq: 1

Gender: M

Reported: 05/07/2005

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 30Y

Onset Date: 12/09/2003

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CEPHAZOLIN SODIUM (Suspected)		Reason: Otr&nos infec¶sit diseases	
Injection	3.0 Gram	Daily	Intravenous
Batch:	Started: 08/09/2003	Stopped: 12/09/2003	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	15.0 Milligram	Daily	
Batch:	Started: 01/01/2002	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 209543 **Seq:** 1 **Gender:** U
Reported: 06/07/2005 **Weight:** 73.00
Hospitalisation: Required a visit to the doctor **Age:** 74
Onset Date: 23/05/2005 **DOB:** 07/03/1931
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		The patient experienced instability in blood glucose - hyperglycaemia immediately following commencement of Olanzapine.	Olanzapine ceased.
Blood glucose fluctuation			

Medicine Details:

ASTRIX 100 (Other drug)	Reason:
Batch:	Started: Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:
DIAFORMIN (Other drug)	Reason:
Batch:	Started: Stopped:
DIAMICRON (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 209543

Seq: 1

Gender: U

Reported: 06/07/2005

Weight: 73.00

Hospitalisation: Required a visit to the doctor

Age: 74

Onset Date: 23/05/2005

DOB: 07/03/1931

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)

Reason:

2.5 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 209550

Seq: 1

Gender: M

Reported: 06/07/2005

Weight: 0.00

Hospitalisation:

Age: 33

Onset Date: 15/12/2004

DOB: 29/08/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient experienced weight gain.	On 16 May 2005 he underwent a left sided subcutaneous mastectomy.

Medicine Details:

OLANZAPINE (Suspected)	Reason: Unspecified schizophrenia
10.0 Milligram	Daily
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210213
Reported: 28/07/2005

Seq: 1

Gender: F
Weight: 0.00
Age: 41
DOB: 04/04/1964
Causality: Causality possible

Hospitalisation:

Onset Date: 20/06/2005
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		The patient developed mild tardive dyskinesia.	

Medicine Details:

CIPRAMIL (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
EFEXOR (Suspected)	Reason:
	Oral
Batch:	Started: Stopped:
SEROQUEL (Suspected)	Reason: Unspecified psychosis
Tablet	600.0 Milligram Daily Oral
Batch:	Started: S TERM Stopped: 0
OLANZAPINE (Suspected)	Reason:
	5.0 Milligram Daily Oral
Batch:	Started: 11/09/2004 Stopped: 29/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210256 **Seq:** 1 **Gender:** M
Reported: 29/07/2005 **Weight:** 67.00
Hospitalisation: Required a visit to the doctor **Age:** 68
Onset Date: 22/06/2005 **DOB:** 02/03/1937
Outcome: Recovered 05/07/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		The patient experienced marked hyperglycaemia two weeks after commencing Olanzapine. Home glucose monitoring is usually 7 or 8 mmol. He had a rapid increase to max 17.5 mmol/L.	Olanzapine ceased.

Medicine Details:

CARBAMAZEPINE (Other drug)	Reason: Unspecifid affective psychosis
Batch:	Started: Stopped:
TRITACE (Other drug)	Reason: Essential benign hypertension
Batch:	Started: Stopped:
ASPIRIN (Other drug)	Reason: Prophylactic inoculation and vaccination
Batch:	Started: Stopped:
DIAMICRON (Other drug)	Reason: Diabetes mellitus
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210256	Seq: 1	Gender: M
Reported: 29/07/2005		Weight: 67.00
Hospitalisation: Required a visit to the doctor		Age: 68
Onset Date: 22/06/2005		DOB: 02/03/1937
Outcome: Recovered	05/07/2005	Causality: Causality probable

Reaction Details:

Medicine Details:

DIABEX (Other drug)		Reason:	Diabetes mellitus
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	Unspecifid affective psychosis
	10.0 Milligram	Daily	
Batch:	Started: 09/06/2005	Stopped: 30/06/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210332 **Seq:** 1 **Gender:** M
Reported: 02/08/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 39
Onset Date: 30/06/2005 **DOB:** 09/05/1966
Outcome: Recovered 04/07/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis		Patient developed drug-induced hepatitis.	Ceased Mirtazapine, Olanzapine, Valproate, Carbamazepine, Cephalexin. Monitor, ultrasound.
Autoimmune hepatitis			

Medicine Details:

MIRTAZAPINE (Suspected)	Reason: Depression
Batch:	Started: 22/06/2005 Stopped: 28/06/2005 0
OLANZAPINE (Suspected)	Reason: Depression
Batch:	Started: 22/06/2005 Stopped: 28/06/2005 0
SODIUM VALPROATE (Suspected)	Reason: Depression
Batch:	Started: 22/06/2005 Stopped: 28/06/2005 0
CARBAMAZEPINE (Suspected)	Reason: Depression
Batch:	Started: 22/06/2005 Stopped: 28/06/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210332

Seq: 1

Gender: M

Reported: 02/08/2005

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 39

Onset Date: 30/06/2005

DOB: 09/05/1966

Outcome: Recovered

04/07/2005

Causality: Causality possible

Reaction Details:

Medicine Details:

CEPHALEXIN (Suspected)

Reason: Other prophylactic procedures

Batch:

Started: 13/06/2005

Stopped: 29/06/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210448 **Seq:** 1 **Gender:** M
Reported: 05/08/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 30
Onset Date: 24/05/2005 **DOB:** 28/06/1974
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	The patient experienced neutropenia.	Olanzapine ceased.

Medicine Details:

PARACETAMOL (Other drug)		Reason: Pain	
Antigen unit			
Batch:	Started:	Stopped:	
LORAZEPAM (Other drug)		Reason: Otr spec symp psychopathol nec	
1.0 Milligram			
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
10.0 Milligram		Daily	
Batch:	Started: 22/05/2005	Stopped: 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/08/2005	Other data				ANC - 22/05/05 - 3.97 and 25/05/05 0.96.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210508 **Seq:** 1 **Gender:** M
Reported: 08/08/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 23
Onset Date: 14/07/2005 **DOB:** 13/08/1981
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	The patient had a five day history of nausea, vomiting, thirst and polyurea. He was diagnosed with diabetic ketoacidosis.	
Diabetic ketoacidosis	Caused or prolonged inpatient hospitalisation		
Polyuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression
	50.0 Milligram Daily	
Batch:	Started:	Stopped: 01/07/2005
STELAZINE (Other drug)		Reason: Unspecified schizophrenia
	5.0 Milligram Daily	
Batch:	Started: 15/07/2004	Stopped: 01/07/2005
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
	20.0 Milligram Daily Oral	
Batch:	Started: 15/07/2004	Stopped: 19/07/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/08/2005	Serum glucose				BSL = 18.3, pH = 7.13, Lactate = 1.8, K+ = 3.6

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 210508 **Seq:** 1 **Gender:** M
Reported: 08/08/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 23
Onset Date: 14/07/2005 **DOB:** 13/08/1981
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thirst	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZOLOFT (Other drug)		Reason: Depression
	50.0 Milligram	Daily
Batch:	Started:	Stopped: 01/07/2005
STELAZINE (Other drug)		Reason: Unspecified schizophrenia
	5.0 Milligram	Daily
Batch:	Started: 15/07/2004	Stopped: 01/07/2005
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia
	20.0 Milligram	Daily Oral
Batch:	Started: 15/07/2004	Stopped: 19/07/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 210522

Seq: 1

Gender: M

Reported: 09/08/2005

Weight: 0.00

Hospitalisation:

Age: 27Y

Onset Date: 15/07/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Patient developed arrhythmia after beginning Zyprexa a couple of years ago.	

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210550 **Seq:** 1 **Gender:** M
Reported: 10/08/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 43
Onset Date: 12/07/2005 **DOB:** 03/05/1962
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Patient experienced prescribed overdose, cardiac failure and cardiomyopathy.	Olanzapine dose reduced to 10mg daily and Trifluoperazine dose reduced to 5mg daily.
Cardiac failure	Caused or prolonged inpatient hospitalisation		
Cardiomyopathy	Caused or prolonged inpatient hospitalisation		

Medicine Details:

STELAZINE (Other drug)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
HALOPERIDOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	30.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210569 **Seq:** 1 **Gender:** M
Reported: 11/08/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 37
Onset Date: 01/04/2005 **DOB:** 19/02/1968
Outcome: Recovered 15/08/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophilia	Caused or prolonged inpatient hospitalisation	Neutrophilia suspected.	Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected)	Reason:
Tablet	Milligram
Batch:	Started: Stopped: 17/06/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 210695 **Seq:** 1 **Gender:** M
Reported: 15/08/2005 **Weight:** 60.00
Hospitalisation: Required a visit to the doctor **Age:** 14
Onset Date: 15/10/2004 **DOB:** 03/05/1990
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed		The patient developed acute urinary retention lasting a couple of days when dose of Olanzapine was temporarily increased.	
Urinary retention			

Medicine Details:

HALOPERIDOL (Other drug)		Reason: Unspecified psychosis	
Batch:	Started: 15/10/2004	Stopped:	
OLANZAPINE (Other drug)		Reason: Unspecified psychosis	
	20.0 Milligram		
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 210847

Seq: 1

Gender: F

Reported: 17/08/2005

Weight: 47.00

Hospitalisation:

Onset Date: 03/08/2005

Age: 19

DOB: 28/04/1986

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed		The patient developed acne. A large acneiform lesion first started after increase in dose of Olanzapine from 10mg to 15mg.	Nil.

Medicine Details:

Lexapro (Other drug)	Reason: Phobic neurosis
10.0 Milligram	Daily
Oral	
Batch:	Started:
	Stopped: 18/07/2005
OLANZAPINE (Suspected)	Reason:
15.0 Milligram	Daily
Batch:	Started: 01/08/2005
	Stopped: Ongoing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Previous treatment with SSRI.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211097
Reported: 25/08/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 08/08/2005

Age: 46

DOB: 27/02/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia Blood creatine phosphokinase incr Neuroleptic malignant syndrome Pyrexia		Patient experienced tachycardia 90-110, elevated creatinine kinase reported as 246, suspected neuroleptic malignant syndrome.	Clopine withheld.

Medicine Details:

LORAZEPAM (Other drug)		Reason:	
Tablet	6.0 Milligram	Oral	
Batch:	Started:	Stopped:	0
CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
PARACETAMOL (Other drug)		Reason:	
Tablet	4.0 Gram	Oral	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	20.0 Milligram	Oral	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211097

Seq: 1

Gender: M

Reported: 25/08/2005

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date: 08/08/2005

DOB: 27/02/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

Aripiprazole (Suspected)		Reason:	
Tablet	15.0 Milligram	Oral	
Batch:	Started:	Stopped:	0
QUETIAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOPINE (Suspected)		Reason:	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 26/07/2005	Stopped:	09/08/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211157

Seq: 1

Gender: M

Reported: 29/08/2005

Weight: 0.00

Hospitalisation:

Onset Date: 01/03/2005

Age: 61Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation	The patient experienced rolling of the tongue, tremor of the hands and chest pain.	
Chest pain	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZEPAM (Other drug)		Reason:	
Tablet	10.0 Milligram	Oral	
Batch:	Started: 15/09/2004	Stopped:	
ISOSORBIDE DINITRATE (Other drug)		Reason:	
Tablet	60.0 Milligram	Oral	
Batch:	Started: 15/09/2004	Stopped:	
DILTIAZEM HYDROCHLORIDE (Other drug)		Reason:	
Capsule	180.0 Milligram	Oral	
Batch:	Started: 15/09/2004	Stopped:	
METOPROLOL TARTRATE (Other drug)		Reason:	
Tablet	50.0 Milligram	Oral	
Batch:	Started: 15/09/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211157

Seq: 1

Gender: M

Reported: 29/08/2005

Weight: 0.00

Hospitalisation:

Age: 61Y

Onset Date: 01/03/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

FLUPENTHIXOL DECANOATE (Suspected)		Reason:	
Injection	50.0 Milligram	Weekly	
Batch:	Started: 15/09/2004	Stopped:	
TRIFLUOPERAZINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started: 15/09/2004	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 15/09/2004	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211221

Seq: 1

Gender: M

Reported: 31/08/2005

Weight: 0.00

Hospitalisation:

Onset Date: 31/07/2005

Age: 41Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Priapism		The patient experienced priapism.	

Medicine Details:

LITHIUM CARBONATE (Other drug)				Reason:	
Batch:		Started:		Stopped:	
VENLAFAXINE HYDROCHLORIDE (Other drug)				Reason:	
Batch:		Started:		Stopped:	
ZYPREXA (Suspected)				Reason: Unspecifid affective psychosis	
		2.5 Milligram		Daily Oral	
Batch:		Started: 15/07/2005		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211380 **Seq:** 1 **Gender:** M
Reported: 06/09/2005 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 23
Onset Date: 21/08/2005 **DOB:** 21/09/1981
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient had a seizure, was found frothing at the mouth and had unresponsive pupils approximately four weeks after commencing Clozaril. He had not received his previous evening dose as, according to his mother, he had been in a 'bad mood' and upset.	Taken to casualty department for post-ictal monitoring.
Blood prolactin increased Drug withdrawal syndrome Foaming at mouth			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
CLOZARIL (Suspected)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started: 28/07/2005	Stopped:	21/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/09/2005	Other data				Clozapine 0.18, Norclozapine 0.12
06/09/2005	Prolactin	<400	22/08/2005	444	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211459
Reported: 05/09/2005

Seq: 1

Gender: F
Weight: 45.00
Age: 82
DOB: 18/12/1922
Causality: Causality possible

Hospitalisation:

Onset Date: 16/08/2005
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced increased liver function tests	Ceased Olanzapine

Medicine Details:

HEPARIN SODIUM (Other drug)		Reason:	
Injection	10.0 Thousand Internal	Subcutaneous	
Batch:	Started: 07/08/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Wafer	2.5 Milligram Daily	Sublingual	
Batch:	Started: 12/08/2005	Stopped: 16/08/2005	0
Hivita Liquivita Tonic (Suspected)		Reason:	
Oral Liquid	30.0 Millilitre Daily	Oral	
Batch:	Started: 12/08/2005	Stopped: 16/08/2005	
PARACETAMOL (Suspected)		Reason:	
	4.0 Gram Daily		
Batch:	Started: 09/08/2005	Stopped: 17/08/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/09/2005	ALT = SGPT		16/08/2005	1200	
05/09/2005	AST = SGOT		16/08/2005	1200	
05/09/2005	Albumin		16/08/2005	33	
05/09/2005	Bilirubin		16/08/2005	16	
05/09/2005	GGT = SGGT =		16/08/2005	65	
05/09/2005	Protein		16/08/2005	62	
05/09/2005	SAP = ALP		16/08/2005	163	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 211459

Seq: 1

Gender: F

Reported: 05/09/2005

Weight: 45.00

Hospitalisation:

Age: 82

Onset Date: 16/08/2005

DOB: 18/12/1922

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

TRIMETHOPRIM (Suspected)

Reason:

300.0 Milligram

Daily

Batch:

Started: 07/08/2005

Stopped: 08/08/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211557 **Seq:** 1 **Gender:** F
Reported: 09/09/2005 **Weight:** 83.00
Hospitalisation: Required a visit to the doctor **Age:** 52
Onset Date: 15/06/2005 **DOB:** 10/03/1953
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Abdominal distension Dry mouth Oedema peripheral Thirst		Patient experienced mildly deranged LFT, swelling of leg and weight gain, bloated, dry mouth and thirsty.	Stopped Zyprexa and increased fluids.

Medicine Details:

Lexapro (Other drug)	Reason: Depression
30.0 Milligram	Oral
Batch:	Started: 15/02/2005 Stopped:
STILNOX (Other drug)	Reason: Specific disorders of sleep
Tablet	10.0 Milligram Oral
Batch:	Started: Stopped:
Symbicort Turbuhaler 200/6 (Other drug)	Reason: Asthma
Inhalation	4.0 Dose Unspecified Inhalation
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason: Anxiety neurosis
2.5 Milligram	Daily
Batch:	Started: 09/06/2005 Stopped: 02/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211557

Seq: 1

Gender: F

Reported: 09/09/2005

Weight: 83.00

Hospitalisation: Required a visit to the doctor

Age: 52

Onset Date: 15/06/2005

DOB: 10/03/1953

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ALPRAZOLAM (Suspected)

Reason: Otr respiratory systm diseases

Tablet

4.0 Milligram

Daily

Oral

Batch:

Started: 09/06/2005

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 211777

Seq: 1

Gender: F

Reported: 20/09/2005

Weight: 0.00

Hospitalisation:

Age: 70Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		Approximately two weeks after beginning Olanzapine, the patient deteriorated rapidly and at the time of this report, she is so severely sedated that she is slumped in a chair and cannot rise from the chair. The patient has also developed a urinary tract infection.	
Urinary tract infection			

Medicine Details:

ARICEPT (Suspected)		Reason: Unspecified psychosis	
Tablet		Oral	
Batch:	Started:	Stopped:	Continuing.
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2005	S TERM	Stopped: Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 211865

Seq: 1

Gender: F

Reported: 22/09/2005

Weight: 0.00

Hospitalisation:

Age: 53

Onset Date: 26/07/2005

DOB: 27/07/1951

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased	Caused or prolonged inpatient hospitalisation	Developed elevated blood glucose and elevated triglyceride levels	
Overdose	Caused or prolonged inpatient hospitalisation	The patient was prescribed an overdose of Olanzapine,	Corrective treatment for the event included low doses of titrated Gliclazide and Atorvastatin Calcium. Zyprexa was discontinued and Quetiapine treatment restarted.

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
	1.0 Gram		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
22/09/2005	Cholesterol		15/07/2005	6.47	
22/09/2005	Cholesterol		12/08/2005	7.5	
22/09/2005	Serum glucose		15/07/2005	9	
22/09/2005	Serum glucose		12/08/2005	13.3	
22/09/2005	Triglyceride		15/07/2005	2.3	
22/09/2005	Triglyceride		12/08/2005	8.13	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 211865

Seq: 1

Gender: F

Reported: 22/09/2005

Weight: 0.00

Hospitalisation:

Age: 53

Onset Date: 26/07/2005

DOB: 27/07/1951

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood triglycerides increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
	1.0 Gram		
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 15/07/2005	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 211931 **Seq:** 1 **Gender:** M
Reported: 23/09/2005 **Weight:** 56.00
Hospitalisation: Admitted to hospital **Age:** 43Y
Onset Date: 27/06/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient experienced neutropenia.	Olanzapine ceased.

Medicine Details:

RITONAVIR (Other drug)	Reason:
Batch:	Started: Stopped:
Tenofovir disoproxil fumarate (Other drug)	Reason:
Batch:	Started: Stopped:
RANITIDINE (Other drug)	Reason: Other diseases of esophagus
Batch:	Started: Stopped:
GEMFIBROZIL (Other drug)	Reason: Othr&unspec metabolic diseases
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/09/2005	Neutrophils		27/06/2005	1.25	Neutrophil count - 2.25.
23/09/2005	Neutrophils		28/06/2005	1.31	Neutrophil count - 2.25.
23/09/2005	Neutrophils		29/06/2005	0.93	Neutrophil count - 2.25.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211931

Seq: 1

Gender: M

Reported: 23/09/2005

Weight: 56.00

Hospitalisation: Admitted to hospital

Age: 43Y

Onset Date: 27/06/2005

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

BACTRIM DS (Other drug)		Reason: Other prophylactic procedures	
Batch:	Started:	Stopped:	
TRIZIVIR (Other drug)		Reason:	
Batch:	Started:	Stopped:	
AZITHROMYCIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
CITALOPRAM HYDROBROMIDE (Suspected)		Reason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 24/06/2005	Stopped: 29/06/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 211931 **Seq:** 1

Reported: 23/09/2005

Hospitalisation: Admitted to hospital

Onset Date: 27/06/2005

Outcome: Unknown

Gender: M

Weight: 56.00

Age: 43Y

DOB:

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)

Reason: Hallucinations

Tablet

5.0 Milligram

Daily

Oral

Batch:

Started: 24/06/2005

Stopped: 29/06/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212056

Seq: 1

Gender: F

Reported: 28/09/2005

Weight: 0.00

Hospitalisation:

Onset Date: 14/03/2005

Age: 70

DOB: 20/02/1935

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		The patient experienced agitation, fever, diaphoresis, shivering, hyperreflexia and restlessness following increasing of Sertraline dose. She was taking 100 mg daily on 2 March 2005 and the dose was increased to 125 mg on 4 March 2005.	Sertraline ceased, Phenergan given for rash.
Chills			
Headache			
Hyperhidrosis			
Hyperreflexia			
Pyrexia			
Rash			

Medicine Details:

LACTULOSE (Other drug)		Reason:	
	20.0 Milligram		
Batch:	Started: 04/03/2005	Stopped:	
SERTRALINE HYDROCHLORIDE (Other drug)		Reason: Depression	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 02/03/2005	Stopped: 14/03/2005	
ZOPICLONE (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 11/03/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 11/03/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212056

Seq: 1

Gender: F

Reported: 28/09/2005

Weight: 0.00

Hospitalisation:

Age: 70

Onset Date: 14/03/2005

DOB: 20/02/1935

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness			
Serotonin syndrome			
Therapy regimen changed			

Medicine Details:

LACTULOSE (Other drug)		Reason:	
	20.0 Milligram		
Batch:	Started: 04/03/2005	Stopped:	
SERTRALINE HYDROCHLORIDE (Other drug)		Reason: Depression	
Tablet	125.0 Milligram	Daily	Oral
Batch:	Started: 02/03/2005	Stopped: 14/03/2005	
ZOPICLONE (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 11/03/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 11/03/2005	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212062

Seq: 1

Gender: F

Reported: 28/09/2005

Weight: 70.00

Hospitalisation:

Onset Date: 01/09/2005

Age: 56

DOB: 29/01/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness Agitation Clonus Hyperhidrosis Hypertonia Serotonin syndrome		Patient experienced stiffness, agitation, sweating, clonus ++ increased tone, serotonin syndrome or NMS.	Ceased all medication, ICU.

Medicine Details:

OLANZAPINE (Suspected)		Reason:	Manic-depression psycho,manic	
Batch:	Started:	18/08/2005	Stopped:	08/09/2005
DOXEPIN HYDROCHLORIDE (Suspected)		Reason:		
Batch:	Started:		Stopped:	08/09/2005
AMITRIPTYLINE HYDROCHLORIDE (Suspected)		Reason:		
Batch:	Started:		Stopped:	08/09/2005
MELLERIL (Suspected)		Reason:		
Batch:	Started:		Stopped:	08/09/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212062

Seq: 1

Gender: F

Reported: 28/09/2005

Weight: 70.00

Hospitalisation:

Age: 56

Onset Date: 01/09/2005

DOB: 29/01/1949

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

RISPERIDONE (Suspected)		Reason: Otr spec symp psychopathol nec	
Batch:	Started: 28/08/2005	Stopped: 08/09/2005	
LITHIUM CARBONATE (Suspected)		Reason: Manic-depression psycho,manic	
Tablet	1.0 Gram	Daily	Oral
Batch:	Started: 18/08/2005	Stopped: 08/09/2005	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 212132

Seq: 1

Gender: M

Reported: 04/10/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date: 01/06/2004

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis		The patient experienced 'nephrotic pancreatitis'.	

Medicine Details:

ZYPREXA (Suspected)	Reason:	Oral
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212133

Seq: 1

Gender: M

Reported: 04/10/2005

Weight: 90.00

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Approximately six months after initiating Olanzapine treatment the patient gained 10 to 20 kg of weight. He became very depressed because of his weight gain.	Olanzapine ceased, changed to Quetiapine.then to lithium and risperidone

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
15.0 Milligram	Daily
Oral	
Batch:	Started: 15/07/2003
	Stopped: 15/08/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212135

Seq: 1

Gender: M

Reported: 29/09/2005

Weight: 100.00

Hospitalisation:

Age: 21Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Six months after initiating Olanzapine treatment the patient gained 10 to 20 kg of weight. The patient became depressed because of his weight gain.	Olanzapine ceased, changed treatment to Quetiapine.

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified schizophrenia
15.0 Milligram	Daily
Oral	
Batch:	Started: 15/03/2004
	Stopped: 15/02/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212206
Reported: 05/10/2005
Hospitalisation:
Onset Date: 25/07/2005
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 17
DOB: 24/09/1987
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache	Caused or prolonged inpatient hospitalisation	Raised CK (931U/L). Tachycardia (122bpm). Headaches. Hypertension (175/90).	Zyprexa was ceased; Antipsychotic medication changed to Seroquel
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Hypertension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATIVAN (Other drug)		Reason: Anxiety neurosis	
Tablet	2.0 Milligram	3 times	Oral
Batch:	Started: 21/07/2005	Stopped:	0
AROPAX (Other drug)		Reason: Depression	
Tablet	40.0 Milligram	1 time	Oral
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	1 time	Oral
Batch:	Started: 22/07/2005	Stopped: 25/07/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
05/10/2005	Creatine kinase		28/07/2005	CK 431U/L.	
05/10/2005	Creatine kinase		30/07/2005	CK 342U/L.	
05/10/2005	Creatine kinase		25/07/2005	CK 931U/L	

Additional Information:

Report 212222 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212267
Reported: 06/10/2005

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 26/08/2005

Age: 24

DOB: 24/09/1980

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced a seizure and showed changes on electroencephalogram indicative of abnormal generalised epilepsy. Also developed neutropenia and leucopenia.	Patient weaned off Olanzapine slowly. Sodium valproate as anticonvulsant
Leukopenia			
Neutropenia			

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 25/07/2005	Stopped: 15/09/2005	0
OLANZAPINE (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/10/2005	Electroencephalogram				alpha activity at 8cps was symmetrical and attenuated on eye opening. Widespread slow activity was intermixed at 2-6cps. Generalised paroxysmal episodes of synchronous and symmetrical 3-4cps higher amplitude slow activity seen at rest, accompanied by very low amplitude bilateral spikes which were more prominent bifrontally. Cardiac rhythm strip;tachycardia 120 rising to 132 with hyperventilation
06/10/2005	Neutrophils		28/11/2005	1.42	

Additional Information:

Febrile convulsion as infant



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212267

Seq: 1

Gender: M

Reported: 06/10/2005

Weight: 0.00

Hospitalisation:

Onset Date: 26/08/2005

Age: 24

Outcome: Unknown

DOB: 24/09/1980

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 25/07/2005	Stopped: 15/09/2005	0
OLANZAPINE (Suspected)		Reason:	
	15.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/10/2005	Serum drug level				Sep 2005, Clozapine level 890 ng/ml and Sep 2005 Clozapine level 460 ng/ml.
06/10/2005	White blood cells		28/11/2005	3.30	

Additional Information:

Febrile convulsion as infant



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 212450

Seq: 1

Gender: M

Reported: 12/10/2005

Weight: 74.50

Hospitalisation:

Age: 55Y

Onset Date: 15/08/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Since commencing Olanzapine treatment the patient has gained 7 kg.	Olanzapine dosage decreased to 2.5 mg daily.

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
5.0 Milligram	Daily
Oral	
Batch:	Started: 15/08/2005
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Bipolar disorder and diabetes. Taking unspecified medication for the treatment of diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 212511

Seq: 1

Gender: M

Reported: 13/10/2005

Weight: 89.00

Hospitalisation:

Age: 27

Onset Date: 16/09/2005

DOB: 16/12/1977

Outcome: Recovered

24/09/2005

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blepharospasm		Patient experienced continued muscle spasm in left eyelid.	Discontinued Zyprexa.

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 15/09/2005	Stopped: 24/09/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previously taken Olanzapine 4 years ago (duration of therapy then was approx 2-3 months) - unsure of adverse effects at that time but none suspected.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212584 **Seq:** 1 **Gender:** M
Reported: 14/10/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/09/2005 **DOB:** 22/07/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Doctor was reducing dose from 15mg to 10mg with addition of Aripiprazole 10mg. For three days prior to admission, patient was experiencing increased mood, concentration, energy which gradually developed to pacing at night and reduced sleep. On presentation he had a facial twitch, sweating, bilateral coarse tremor, raised creatinine kinase (1958) and some cognitive impairment.	Withdrawal of all antipsychotics, supportive measures monitoring.

Medicine Details:

ZYPREXA (Suspected)		Reason: Paranoid type schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 15/07/2003	Stopped: 15/09/2005	0
Abilify (Suspected)		Reason: Paranoid type schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 15/08/2005	Stopped: 15/09/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212584 **Seq:** 1 **Gender:** M
Reported: 14/10/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/09/2005 **DOB:** 22/07/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Cognitive disorder	Caused or prolonged inpatient hospitalisation		
Muscle twitching	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason: Paranoid type schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 15/07/2003	Stopped: 15/09/2005	0
Abilify (Suspected)		Reason: Paranoid type schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 15/08/2005	Stopped: 15/09/2005	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 212584 **Seq:** 1 **Gender:** M
Reported: 14/10/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/09/2005 **DOB:** 22/07/1976
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason: Paranoid type schizophrenia	
	10.0 Milligram	Daily	
Batch:	Started: 15/07/2003	Stopped: 15/09/2005	0
Abilify (Suspected)		Reason: Paranoid type schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 15/08/2005	Stopped: 15/09/2005	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 212647

Seq: 1

Gender: M

Reported: 17/10/2005

Weight: 0.00

Hospitalisation:

Onset Date: 07/05/2005

Age: 56

DOB: 22/03/1949

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	On 7 May 2005 the patient was found dead, the cause of death was unknown.	

Medicine Details:

SEROQUEL (Suspected)		Reason: Unspecifid affective psychosis	
Tablet	800.0 Milligram	Daily	Oral
Batch:	Started: 10/06/2004	Stopped: 20/04/2005	0
LITHIUM CARBONATE (Suspected)		Reason:	
	1.0 Gram	Daily	Oral
Batch:	Started: 16/08/2004	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	Oral
Batch:	Started: 20/04/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 212673 **Seq:** 1 **Gender:** F
Reported: 18/10/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 48Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Higher than recommended dose used	Doctors considering switching the patient to Clozapine for efficacy reasons.
Tardive dyskinesia	Caused or prolonged inpatient hospitalisation	The patient experienced tardive dyskinesia, restlessness and was not responding sufficiently to Olanzapine treatment.	
Drug effect decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Other drug)		Reason: Unspecified schizophrenia	
Batch:	Started: 15/01/2005	Stopped:	Continuing.
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
	30.0 Milligram	Daily	Oral
Batch:	Started: 15/01/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 212673 **Seq:** 1 **Gender:** F
Reported: 18/10/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 48Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Risperdal Consta (Other drug)		Reason: Unspecified schizophrenia	
Batch:	Started: 15/01/2005	Stopped:	Continuing.
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
	30.0 Milligram	Daily	Oral
Batch:	Started: 15/01/2005	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 213378

Seq: 1

Gender: M

Reported: 14/11/2005

Weight: 0.00

Hospitalisation:

Age: 35Y

Onset Date: 15/10/2005

DOB:

Outcome: Death, maybe drug

10/11/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	Patient committed suicide.	

Medicine Details:

Risperdal Consta (Suspected)		Reason:	
Injection			Intramuscular
Batch:	Started:	S TERM	Stopped: 15/10/2005
SODIUM VALPROATE (Suspected)		Reason:	
Batch:	Started:		Stopped:
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 213519

Seq: 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased	Caused or prolonged inpatient hospitalisation	Patient's Blood glucose test was 43 MMOL/L, also experienced swollen ankles (joint swelling).	Xyprexa was ceased. Treated with insulin therapy.
Gravitational oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213524

Seq: 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Onset Date: 02/04/2005

Age: 43

DOB: 23/08/1961

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome Blood creatine phosphokinase incr Hallucination, auditory Leukocytosis Pyrexia Suicidal ideation		The patient experienced suspected Neuroleptic Malignant Syndrome. She had increased temperatures, increased creatine kinase, was having disturbing thoughts, hearing voices and suicidal ideation.	Withheld neuroleptics initially, monitored temperature, BP, pulse, QID. Olanzapine restarted on 7/4/05.

Medicine Details:

Aripiprazole (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 17/03/2005	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2005	ALT = SGPT		02/04/2005	61	
17/11/2005	ALT = SGPT		04/04/2005	51	
17/11/2005	ALT = SGPT		11/04/2005	62	
17/11/2005	AST = SGOT		02/04/2005	36	
17/11/2005	AST = SGOT		04/04/2005	37	
17/11/2005	Creatinine		02/04/2005	0.11	
17/11/2005	Creatinine		11/04/2005	0.09	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213524

Seq: 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Onset Date: 02/04/2005

Age: 43

DOB: 23/08/1961

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

Medication Details:				
Aripiprazole (Suspected)		Reason:		
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 17/03/2005	Stopped:		
OLANZAPINE (Suspected)		Reason:		
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2005	GGT = SGGT =		02/04/2005	158	
17/11/2005	GGT = SGGT =		04/04/2005	125	
17/11/2005	GGT = SGGT =		11/04/2005	109	
17/11/2005	Neutrophils		02/04/2005	5.8	
17/11/2005	Neutrophils		11/04/2005	3.7	
17/11/2005	Neutrophils		04/04/2005	4.4	
17/11/2005	Potassium		02/04/2005	4.1	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213524

Seq: 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Onset Date: 02/04/2005

Age: 43

DOB: 23/08/1961

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

Medication Details:				
Aripiprazole (Suspected)		Reason:		
Tablet	15.0 Milligram	Daily	Oral	
Batch:	Started: 17/03/2005	Stopped:		
OLANZAPINE (Suspected)		Reason:		
Tablet	5.0 Milligram	Daily	Oral	
Batch:	Started:	Stopped:		

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2005	Sodium		02/04/2005	142	
17/11/2005	White blood cells		02/04/2005	9.0	
17/11/2005	White blood cells		04/04/2005	6.8	
17/11/2005	White blood cells		11/04/2005	6.0	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 213565

Seq: 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Age: 48Y

Onset Date: 08/08/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatitis fulminant	Caused or prolonged inpatient hospitalisation	Fulminant hepatitis likely caused by Clarithromycin.	Patient intubated and sedated, NGT, NAC and Folinic Acid. Cholestyramine 8g/tds to help with removal of Arava from GIT. Stopped all anti-rheumatoid medications, and psychotropic medications and pill.

Medicine Details:

FOLIC ACID (Other drug)			Reason:
Batch:	Started:	Stopped:	
CENTRUM TABLETS (Other drug)			Reason:
Batch:	Started:	Stopped:	
OSTELIN 1000 (Other drug)			Reason:
Batch:	Started:	Stopped:	
NEXIUM (Other drug)			Reason:
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2005	ALT = SGPT	<34 u/l	04/08/2005	2621	
17/11/2005	ALT = SGPT	<34 u/l	10/08/2005	1583	
17/11/2005	ALT = SGPT	<34 u/l	23/08/2005	1431	
17/11/2005	Bilirubin	<18 mcml/L	04/08/2005	27	
17/11/2005	Bilirubin	<18 mcml/L	10/08/2005	50	
17/11/2005	Bilirubin	<18 mcml/L	23/08/2005	33	
17/11/2005	GGT = SGGT =	<38 u/l	04/08/2005	118	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 213565

Seq: 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Age: 48Y

Onset Date: 08/08/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

MONOPLUS NOS (Other drug)		Reason:	
Batch:	Started:	Stopped:	0
AMOXIL (Other drug)		Reason:	
Batch:	Started:	Stopped:	
METHOTREXATE (Suspected)		Reason:	
	20.0 Milligram	Weekly	Oral
Batch:	Started:	Stopped:	09/08/2005
ALPRAZOLAM (Suspected)		Reason:	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	09/08/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2005	GGT = SGGT =	<38 u/l	23/08/2005	153	INR - 4.5.
17/11/2005	GGT = SGGT =	<38 u/l	10/08/2005	104	
17/11/2005	International				
17/11/2005	SAP = ALP	32-91 u/l	04/08/2005	88	
17/11/2005	SAP = ALP	32-91 u/l	10/08/2005	84	
17/11/2005	SAP = ALP	32-91 u/l	23/08/2005	90	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213565

Seq: 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Age: 48Y

Onset Date: 08/08/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ARAVAL (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 12/01/2005	Stopped: 09/08/2005	
MOBIC (Suspected)		Reason:	
	7.5 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/08/2005	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/08/2005	
PLAQUENIL (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 12/12/2001	Stopped: 09/08/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213565

Seq: 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Age: 48Y

Onset Date: 08/08/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ARTANE (Suspected)		Reason:	
Tablet	1.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/08/2005	
EFEXOR (Suspected)		Reason:	
	450.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 09/08/2005	
KLACID (Suspected)		Reason:	
	500.0 Milligram	Daily	Oral
Batch:	Started: 31/07/2005	Stopped: 08/08/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213743
Reported: 24/11/2005

Seq: 1

Gender: M
Weight: 70.00
Age: 72Y
DOB:
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Life threatening	Suicide attempt.	

Medicine Details:

EFEXOR (Suspected)		Reason:	
	37.5 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:
EFEXOR-XR (Suspected)		Reason:	
	225.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram	Daily	
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213886 **Seq:** 1 **Gender:** M
Reported: 29/11/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 15/11/2005 **DOB:** 30/10/1976
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia	Caused or prolonged inpatient hospitalisation	Patient experienced proximal muscle weakness, soreness both legs, developed abnormal gait and tremor.	Cogentin.
Muscular weakness	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Wafer	10.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2005	Stopped: 13/11/2005	
VALIUM (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2005	Stopped: 13/11/2005	
ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2005	Stopped: 13/11/2005	
MIDAZOLAM (Suspected)		Reason:	
Injection	1.0 Milligram	Daily	Intravenous
Batch:	Started: 13/11/2005	Stopped: 13/11/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213886 **Seq:** 1

Reported: 29/11/2005

Hospitalisation: Admitted to hospital

Onset Date: 15/11/2005

Outcome: Not yet recovered

Gender: M

Weight: 0.00

Age: 29

DOB: 30/10/1976

Causality: Causality possible

Reaction Details:

Medicine Details:

VALIUM (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 13/11/2005	Stopped:	13/11/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 213952

Seq: 1

Gender: M

Reported: 02/12/2005

Weight: 0.00

Hospitalisation:

Onset Date: 07/09/2005

Age: 24

DOB: 11/01/1981

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation	Raised liver function tests: alkaline phosphatase 195 U/L, ALT 988U/L, Gamma GT 129U/L	Zyprexa & Epilim were ceased
Blood alkaline phosphatase increa	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Suspected)			Reason:	
Tablet	700.0	Milligram	2 times	Oral
Batch:	Started:		Stopped:	07/09/2005
ZYPREXA (Suspected)			Reason:	
Tablet	20.0	Milligram	1 time	Oral
Batch:	Started:		Stopped:	07/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 213963

Seq: 1

Gender: M

Reported: 02/12/2005

Weight: 0.00

Hospitalisation:

Onset Date: 26/02/2005

Age: 32

DOB: 15/01/1973

Outcome: Death, maybe drug

26/02/2000

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Death	Pateint died possibly due to olanzapine and valproic acid, possibly due to a drug interaction.	
Drug interaction	Death		

Medicine Details:

OLANZAPINE (Interaction)	Reason:
Batch:	Started: Stopped:
FLUVOXAMINE MALEATE (Interaction)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Interaction)	Reason:
Batch:	Started: Stopped:
ZUCLOPENTHIXOL ACETATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/12/2005	Serum drug level				Toxicological analysis revealed bloodlevels of 0.58 mg/l of Olanzapine (580 ng/l), which is inconsistent with therapeutic use of Olanzapine, 59 mg/l of Valproic Acid, 0.04 mg/l of Fluvoxamine and 0.03 mg/l of Morphine. No alcohol was detected.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214294

Seq: 1

Gender: F

Reported: 14/12/2005

Weight: 58.00

Hospitalisation:

Onset Date: 29/11/2005

Age: 28

DOB: 25/06/1977

Outcome: Recovered

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Acne		Patient was taking Zyprexa earlier this year and started to get pimples. Once the Zyprexa was ceased mid-year, the pimples cleared up. Upon restarting Zyprexa more recently, the patient noticed the return of pimples. The pimples appear on the face and neck , mainly around the jawline area and upper neck.	Patient treating pimples with over the counter measures such as Benzoly Peroxide gels. Zyprexa ceased.

Medicine Details:

ZYPREXA (Suspected)		Reason: Depression	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 21/11/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug certain rechallenge.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214501 **Seq:** 1 **Gender:** F
Reported: 23/12/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 16Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Suspected neuroleptic malignant syndrome, blood creatine phosphokinase increased and renal impairment.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Renal impairment	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LORAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
MAXOLON (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/12/2005	Creatine				CPK=8500 units and dates not reported.

Additional Information:

Historical drugs: Phenothiazine and Benzodiazepine derivatives.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214539

Seq: 1

Gender: M

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date:

DOB: 09/09/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome		The patient developed chronic serotonin syndrome and severe akathisia.	
Akathisia			

Medicine Details:

PANADEINE FORTE (Other drug)	Reason:
Batch:	Started: Stopped:
NUROFEN (Other drug)	Reason:
Batch:	Started: Stopped:
VALIUM (Other drug)	Reason:
Batch:	Started: Stopped:
NORTRIPTYLINE HYDROCHLORIDE (Suspected)	Reason:
Batch:	Started: Stopped: Oral

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 214539

Seq: 1

Gender: M

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 46

Onset Date:

DOB: 09/09/1959

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

Lexapro (Suspected)		Reason:	
Batch:	Started:	Stopped: Oral	
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214541

Seq: 1

Gender: M

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 26/08/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient experienced akathisia and supersensitivity psychosis. He was cognitively impaired and was unable to access his memories in response to questions. He experienced agitation and aggression, developed elevations in temperature, alterations in alanine amino-transferase, aspartate transferase and elevated creatinine kinase levels. He experienced a grand mal seizure and delirium. He had many episodes of violence and made homicidal and suicidal threats. He experienced visual, tactile and somatic hallucinations.	

Medicine Details:

LITHIUM CARBONATE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 214541

Seq: 1

Gender: M

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 26/08/1975

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression Amnesia Cognitive disorder Delirium Homicidal ideation Psychotic disorder Suicidal ideation			

Medicine Details:

LITHIUM CARBONATE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214552
Reported: 04/01/2006

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 21

DOB: 25/09/1984

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia Hallucination Personality disorder Psychotic disorder		The patient experiences some restlessness. She becomes agitated and suicidal. She thinks her parents in the next room are talking about her. She believes in magic and clairvoyance and thinks she has clairvoyance. She believes in telepathy and sixth sense. She experiences hallucinations and fulfils all the criteria for schizotypal personality disorder.	

Medicine Details:

AROPAX (Suspected)		Reason:	
Tablet	40.0 Milligram	Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214550 is the first sequence to this report.
A half an hour after she takes the Zyprexa tablets she sees visions, sees something fly past and then goes away. She like the Zyprexa.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 214552

Seq: 1

Gender: F

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date:

DOB: 25/09/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness			
Suicide attempt			

Medicine Details:

AROPAX (Suspected)		Reason:	
Tablet	40.0 Milligram	Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
	20.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Report 214550 is the first sequence to this report.

A half an hour after she takes the Zyprexa tablets she sees visions, sees something fly past and then goes away. She like the Zyprexa.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 214558
Reported: 04/01/2006

Seq: 1

Gender: M
Weight: 0.00
Age: 21
DOB: 10/09/1984
Causality: Causality possible

Hospitalisation:

Onset Date:
Outcome: Unknown

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient attempted to kill himself. He was seeing things and hearing things and was violent. If he missed a pill he became restless and energetic.	
Homicidal ideation			
Suicide attempt			

Medicine Details:

VALIUM (Other drug)	Reason:
Batch:	Started: Stopped:
CANNABIS PREPARATION (Other drug)	Reason:
Batch:	Started: Stopped:
ZYPREXA (Suspected)	Reason:
2.5 Milligram Daily	
Batch:	Started: Stopped:
CIPRAMIL (Suspected)	Reason:
Tablet 40.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 214555 is the first sequence to this report and report 214557 is the second sequence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 214561

Seq: 1

Gender: M

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient experienced akathisia and delirium. He suffered depression and agitation and wakes after sleeping only three hours, sleeping no more after that.	
Delirium			

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
RISPERIDONE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
MIRTAZAPINE (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 214840 **Seq:** 1 **Gender:** M
Reported: 11/01/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 42
Onset Date: 07/07/2005 **DOB:** 05/02/1963
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed a high fever (39.4), rigors and gram negative bacilli bacteremia	Olanzapine ceased.
Bacteraemia	Caused or prolonged inpatient hospitalisation		
Chills	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:
COGENTIN (Other drug)	Reason:
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/01/2006	ALT = SGPT		04/07/2005	419	
11/01/2006	AST = SGOT		04/07/2005	79	
11/01/2006	C-Reactive Protein		04/07/2005	79	
11/01/2006	Creatine		08/07/2005	77	
11/01/2006	Eosinophils		08/07/2005	0.02	
11/01/2006	Erythrocyte		04/07/2005	45	
11/01/2006	GGT = SGGT =		04/07/2005	414	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 214840

Seq: 1

Gender: M

Reported: 11/01/2006

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 42

Onset Date: 07/07/2005

DOB: 05/02/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)

Reason: Unspecifid affective psychosis

Tablet

10.0 Milligram

1 time

Oral

Batch:

Started: 18/12/2004

Stopped: 18/12/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
11/01/2006	Lymphocytes		08/07/2005	1.32	
11/01/2006	Monocytes		08/07/2005	0.49	
11/01/2006	Neutrophils		08/07/2005	3.77	
11/01/2006	SAP = ALP		04/07/2005	235	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 214999

Seq: 1

Gender: F

Reported: 17/01/2006

Weight: 57.00

Hospitalisation:

Age: 17

Onset Date: 08/08/2005

DOB: 04/12/1987

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Patient experienced hyperprolactinaemia.	Changed to Quetiapine.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	15.0 Milligram	Daily	
Batch:	Started: 05/08/2005	Stopped: 10/08/2005	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/01/2006	Prolactin	85-575			Prolactin 1986 mu/l.

Additional Information:

FSH, LH & TSH normal. CT head scan non-specific hyperdensity of path pituitary gland.
History: Heavy Amphetamine and marijuana abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215307

Seq: 1

Gender: F

Reported: 27/01/2006

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date:

DOB: 03/10/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		The patient developed impulses to kill herself and was restless. She could not sit down and was pacy. She had panic attacks, violent dreams and would sleep all day.	
Akathisia			

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CANNABIS PREPARATION (Suspected)		Reason:	
Batch:	Started:	Stopped:	
EFEXOR (Suspected)		Reason:	
	175.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 215345

Seq: 1

Gender: F

Reported: 30/01/2006

Weight: 0.00

Hospitalisation:

Onset Date: 10/10/2005

Age: 81

DOB: 03/12/1923

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle twitching		Patient experienced intermittent twitching - generalized twitching after 4 days of Olanzapine.	Ceased Olanzapine.

Medicine Details:

COLOXYL WITH SENNA (Other drug)		Reason:	Constipation
Batch:	Started:	Stopped:	0
PARACETAMOL (Other drug)		Reason:	Pain
Batch:	Started:	Stopped:	
ASPIRIN (Other drug)		Reason:	Other coagulation defects
Batch:	Started:	Stopped:	
PRAVASTATIN SODIUM (Other drug)		Reason:	Othr&unspec metabolic diseases
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 215345 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215345

Seq: 1

Gender: F

Reported: 30/01/2006

Weight: 0.00

Hospitalisation:

Age: 81

Onset Date: 10/10/2005

DOB: 03/12/1923

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

PINDOLOL (Other drug)		Reason: Essential benign hypertension	
Batch:	Started:	Stopped:	
OLANZAPINE (Other drug)		Reason: Unspecified schizophrenia	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 06/10/2005	Stopped: 10/10/2005	

Laboratory Investigations:

Additional Information:

Report 215345 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215351

Seq: 1

Gender: M

Reported: 30/01/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Death, maybe drug

15/07/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression	Death	The patient became violent and suicidal on Zyprexa. If he did not take a dose he manifested supersensitivity psychosis or withdrawal akathisia. At one time, when he ran out, he went akathisia violent, homicidal and suicidal. He committed suicide by hanging in July 2005.	
Akathisia	Death		
Completed suicide	Death		
Drug withdrawal syndrome	Death		
Homicidal ideation	Death		
Psychotic disorder	Death		

Medicine Details:

ZYPREXA (Suspected)		Reason:	
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 215351

Seq: 1

Gender: M

Reported: 30/01/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Death, maybe drug

15/07/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation	Death		

Medicine Details:

ZYPREXA (Suspected)	Reason:		
	40.0 Milligram	Daily	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 215506

Seq: 1

Gender: M

Reported: 02/02/2006

Weight: 0.00

Hospitalisation:

Onset Date: 01/01/2006

Age: 35Y

DOB:

Outcome: Death, maybe drug

06/01/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Death	Patient received Zyprexa 20mg intramuscularly and intramuscular clonazepam 6mg, reporter stated that Zyprexa 20mg should not have happened, it was not provided whether this was an accidental or prescribed overdose. The patient experienced cardiac arrest and died.	

Medicine Details:

CLONAZEPAM (Suspected)		Reason:	
Injection		Intramuscular	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Otr spec symp psychopathol nec	
Injection	20.0 Milligram	Daily	Intramuscular
Batch:	Started: 01/01/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history included diabetes, obesity and was generally poor in health.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215506

Seq: 1

Gender: M

Reported: 02/02/2006

Weight: 0.00

Hospitalisation:

Onset Date: 01/01/2006

Age: 35Y

DOB:

Outcome: Death, maybe drug

06/01/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Death	Patient received Zyprexa 20mg intramuscularly and intramuscular clonazepam 6mg, reporter stated this should not have happened, it was not provided whether this was an accidental or prescribed overdose. The patient experienced cardiac arrest and died.	
Overdose	Death		

Medicine Details:

CLONAZEPAM (Suspected)		Reason:	
Injection		Intramuscular	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Otr spec symp psychopathol nec	
Injection	20.0 Milligram	Daily	Intramuscular
Batch:	Started: 01/01/2006	Stopped:	0

Laboratory Investigations:

Additional Information:

Medical history included diabetes, obesity and was generally poor in health.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215538
Reported: 03/02/2006

Seq: 1

Gender: F
Weight: 40.00

Hospitalisation:

Onset Date: 20/09/2005

Age: 12

DOB: 14/05/1993

Outcome: Recovered

15/12/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		The child experienced urinary incontinence, stress incontinence and nocturnal incontinence.	
Urinary incontinence			
Enuresis			

Medicine Details:

ASCORBIC ACID (Other drug)		Reason:	
Tablet	500.0 Milligram	Oral	
Batch:	Started: 15/07/2005	Stopped:	
ZYPREXA (Suspected)		Reason: Anorexia	
	5.0 Milligram	Daily	
Batch:	Started: 12/08/2005	Stopped: 30/11/2005	0
F.G.F. (Suspected)		Reason:	
	1.0 Dose Unspecified	Daily	
Batch:	Started: 15/07/2005	Stopped: 30/10/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215794
Reported: 13/02/2006

Seq: 1

Gender: F

Weight: 0.00

Hospitalisation:

Age: 57

Onset Date:

DOB: 04/12/1948

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia	Incapacity/disability	The patient developed tardive dyskinesia.	Olanzapine ceased, changed to Seroquel.

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LITHICARB (Other drug)		Reason: Unspecifid affective psychosis	
	1.2 Gram	Daily	Oral
Batch:	Started:	Stopped: 0	
EFEXOR-XR (Other drug)		Reason: Unspecifid affective psychosis	
	300.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
	2.5 Milligram	Daily	
Batch:	Started:	Stopped: 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 215795 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215896 **Seq:** 1 **Gender:** F
Reported: 16/02/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 89
Onset Date: 10/03/2005 **DOB:** 25/04/1915
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium	Caused or prolonged inpatient hospitalisation	Delirium secondary to Olanzapine, superimposed upon dementia, confusion, vagueness and decreased mobility.	Dose reduced to 5mg daily.

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
RALOXIFENE (Other drug)	Reason:
Batch:	Started: Stopped:
SORBITOL (Other drug)	Reason:
Batch:	Started: Stopped:
PARACETAMOL (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 215896

Seq: 1

Gender: F

Reported: 16/02/2006

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 89

Onset Date: 10/03/2005

DOB: 25/04/1915

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Tablet	10.0 Milligram	1 time	Oral
Batch:	Started: 09/03/2005	Stopped: 09/03/2005	
ZYPREXA (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 09/03/2005	Stopped: 10/03/2005	
ZYPREXA (Suspected)		Reason:	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216307

Seq: 1

Gender: F

Reported: 07/03/2006

Weight: 0.00

Hospitalisation:

Age: 24Y

Onset Date: 15/02/2006

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arterial thrombosis limb	Caused or prolonged inpatient hospitalisation	Patient was admitted to hospital due to thrombosis that she had experienced in all major blood vessels of her legs.	Ceased Zyprexa

Medicine Details:

MICROGYNON (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
	1.3 Milligram	Daily	Oral
Batch:	Started:	Stopped: 15/02/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient had a history of brain damage at birth and mild cerebral palsy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216346
Reported: 09/03/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 16/08/2005

Age: 40

DOB: 04/08/1965

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Patient experienced neuroleptic malignant syndrome, tachycardia, blood pressure increased, hypertonia and complaining of stiffness.	Stopped neuroleptics on 16/08/05.
Blood pressure increased	Caused or prolonged inpatient hospitalisation		
Hypertonia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason:	
Tablet	2.0 Gram	Oral	
Batch:	Started: 16/08/2005	Stopped:	
CLONAZEPAM (Other drug)		Reason: Anxiety neurosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 16/08/2005	Stopped:	
ZUCLOPENTHIXOL ACETATE (Suspected)		Reason: Unspecified psychosis	
Injection	200.0 Milligram	1 time	
Batch:	Started: 11/08/2005	Stopped: 12/08/2005	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/03/2006	Creatine		19/08/2005	300	
09/03/2006	Serum drug level		12/08/2005	140	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 216360

Seq: 1

Gender: F

Reported: 09/03/2006

Weight: 0.00

Hospitalisation:

Age: 37Y

Onset Date: 03/03/2006

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alopecia		Hair falling out in clumps	

Medicine Details:

Zyprexa Zydys (Suspected)	Reason:
	1 time Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216399
Reported: 10/03/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date:

DOB: 09/10/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation		Patient had thoughts about killing himself which made him violent, tried to hit someone else, tried to hit a security guard with feelings of killing and tried to do physical damage. Tried to hurt himself and had thoughts of hurting other people. He was walking faster than normal. Experienced aggression, insomnia and was feeling high on Prozac. Also felt anxious and put on more than 20kg.	
Aggression			
Akathisia			

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started: 19/02/2004	Stopped: 19/01/2006	
PROZAC (Suspected)		Reason: Depression	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216399

Seq: 1

Gender: M

Reported: 10/03/2006

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date:

DOB: 09/10/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety Euphoric mood Insomnia Intentional self-injury Weight increased			

Medicine Details:

ZYPREXA (Suspected)		Reason:	
Batch:	Started: 19/02/2004	Stopped: 19/01/2006	
PROZAC (Suspected)		Reason: Depression	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216669

Seq: 1

Gender: M

Reported: 24/03/2006

Weight: 96.00

Hospitalisation:

Age: 44

Onset Date: 17/03/2006

DOB: 25/08/1961

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation	Stopped taking Zyprexa, 5mg tablets. Had severe withdrawal from the medication. Symptoms include extreme anxiety, insomnia, uncontrollable shaking, nausea.	Doctor has resumed Zyprexa at 2.5mg in conjunction with 25mg of Tryptanol.

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified affective psychosis
Tablet	5.0 Milligram Daily Oral
Batch:	Started: 10/09/2005 Stopped: 17/03/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216731
Reported: 28/03/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 11/03/2006

Age: 50

DOB: 09/04/1955

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased	Caused or prolonged inpatient hospitalisation	Patient had been found non-responsive, unconscious, sedated and with frothing at mouth, increased body temperature and an increased CK.	
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason: Unspecified schizophrenia	
Tablet	700.0 Milligram	Daily	Oral
Batch:	Started: 30/08/1995	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
27/03/2006	Creatine		11/03/2006	63000	

Additional Information:

No muscle rigidity.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216787
Reported: 29/03/2006

Seq: 1

Gender: M
Weight: 90.00

Hospitalisation:

Onset Date: 12/03/2006

Age: 50

Outcome: Recovered

23/03/2006

DOB: 09/04/1955

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Patient in hostel was observed to slump from chair- no obvious fitting but described as frothing from the mouth. Lost consciousness for 5 mins. When he awoke- agitated, aggressive. Intubated for airway protection and admitted to ICU. In ICU, elevated CK, acute renal failure,febrile. Neuroleptic malignany syndrome diagnosed. No muscle rigidity.	Intubation, Fluids and mannitol to maintain urine output; dantrolene and bromocriptine
Aggression	Life threatening		
Agitation	Life threatening		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
CLOZAPINE (Suspected)		Reason:	
Tablet	600.0 Milligram	1 time	Oral
Batch:	Started: 31/03/2005	Stopped:	12/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
28/03/2006	Creatine phosphokinase				CK on admission 606 IU/L and peaked at 63328 on the 13/03/2006. Gradually decreased to normal (< 200 IU/L)on 24/03/2006. U&Es, FBE all normal. Micro: blood, urine, sputum, CSF- no growth

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 216787

Seq: 1

Gender: M

Reported: 29/03/2006

Weight: 90.00

Hospitalisation:

Age: 50

Onset Date: 12/03/2006

DOB: 09/04/1955

Outcome: Recovered

23/03/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Life threatening		

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
PAROXETINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
CLOZAPINE (Suspected)		Reason:	
Tablet	600.0 Milligram	1 time	Oral
Batch:	Started: 31/03/2005	Stopped:	12/03/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 216863 **Seq:** 1 **Gender:** M
Reported: 31/03/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced neuroleptic malignant syndrome.	Transferred to ICU.

Medicine Details:

Medication Details:			
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	
HALOPERIDOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	
VALIUM (Suspected)		Reason:	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 216893

Seq: 1

Gender: M

Reported: 03/04/2006

Weight: 110.00

Hospitalisation:

Age: 25Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Incorrect dose administered		Dose used higher than recommended	
Depression		Experienced depression which was described as a "major problem"	citalopram
Weight increased		Since starting Zyprexa patient has gained five and a half stone in weight increased and prescribed overdose.	Zyprexa discontinued.
Increased appetite			

Medicine Details:

DIAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	60.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 216894

Seq: 1

Gender: M

Reported: 03/04/2006

Weight: 0.00

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		After commencing Zyprexa pateint experienced a seizure.	

Medicine Details:

SEROQUEL (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
EFEXOR (Suspected)		Reason:	
		Oral	
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Suspected)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient's medical history includes the patient experiencing extreme agitation whilst receiving Lithium. This report 216894 is a duplicate of 216945.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 216944 **Seq:** 1 **Gender:** F
Reported: 04/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 54
Onset Date: 08/03/2006 **DOB:** 24/09/1951
Outcome: Recovered 15/03/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	Ceased Olanzapine and monitor with FBC.

Medicine Details:

CEPHALEXIN (Other drug)		Reason: Othr diseases of urinary tract	
	250.0 Milligram		
Batch:	Started: 19/12/2005	Stopped:	0
THIAMINE (Other drug)		Reason:	
	100.0 Milligram		
Batch:	Started: 15/12/2005	Stopped:	
MULTIVITAMINS (Other drug)		Reason:	
Tablet	1.0 Dose Unspecified	Oral	
Batch:	Started: 22/12/2005	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 18/10/2004	Stopped:	09/03/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/04/2006	Neutrophils		08/03/2006	0.85	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 216949

Seq: 1

Gender: M

Reported: 04/04/2006

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 09/06/1971

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient received no Clozaril for 2.5-3 weeks when he was given Olanzapine in hospital. The patient then developd NMS (neuroleptic malignant syndrome) with a raised temperature and raised CK.	benzodiazapine
Neuroleptic malignant syndrome		Suspected	
Blood creatine phosphokinase incr			

Medicine Details:

OLANZAPINE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 216948 is the first sequence to this report.
Patient was already in hospital at time of the reaction.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 217175 **Seq:** 1 **Gender:** F
Reported: 07/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 65Y
Onset Date: 15/02/2006 **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Joint swelling	Caused or prolonged inpatient hospitalisation	The patient experienced swollen ankle, pain (location unknown), fever and raised c-reactive protein.	
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Anxiety neurosis
5.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Suspect drug certain rechallenge.
Medical condition: Bipolar disorder and rheumatoid arthritis.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 217175 **Seq:** 1 **Gender:** F
Reported: 07/04/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 65Y
Onset Date: 15/02/2006 **DOB:**
Outcome: Unknown **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Anxiety neurosis
5.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Suspect drug certain rechallenge.
Medical condition: Bipolar disorder and rheumatoid arthritis.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 217538 **Seq:** 1 **Gender:** F
Reported: 20/04/2006 **Weight:** 48.50
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: 08/02/2006 **DOB:** 28/07/1981
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis	Life threatening	Bilateral femoral, iliac and right popliteal and right calf DVT's on sonogram.	Clexane, then Warfarin.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	1.3 Milligram	Daily	Oral
Batch:	Started: 21/10/2003	Stopped: 08/02/2006	
MICROGYNON 30 ED (Suspected)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	Stopped: 08/02/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 217552 **Seq:** 1 **Gender:** M
Reported: 20/04/2006 **Weight:** 70.00
Hospitalisation: Required a visit to the doctor **Age:** 41
Onset Date: 05/04/2006 **DOB:** 13/06/1964
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Choreoathetosis		Patient developed acute fairly severe choreo-athetoid movements.	Given Benztropine 2mg IM and Olanzapine was discontinued.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Manic-depression psycho,manic	
	20.0 Milligram	1 time	Oral
Batch:	Started: 05/04/2006	Stopped: 05/04/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 217840 **Seq:** 1 **Gender:** M
Reported: 02/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: 17/02/2003 **DOB:** 27/12/1978
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eye infection	Incapacity/disability	Frequent eye infections	
Diabetes mellitus insulin-dependen	Incapacity/disability	Patient diagnosed with insulin dependent diabetes. Patient also reported to have experienced difficulty sleeping, anxiety, depression and frequent sweating.	
Anxiety	Incapacity/disability		
Depression	Incapacity/disability		
Hyperhidrosis	Incapacity/disability		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 05/09/1999	Stopped: 20/02/2003	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 217840 **Seq:** 1 **Gender:** M
Reported: 02/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 24
Onset Date: 17/02/2003 **DOB:** 27/12/1978
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia	Incapacity/disability		
Ketoacidosis	Incapacity/disability		
Renal impairment	Incapacity/disability		
Weight increased	Incapacity/disability		

Medicine Details:

SERTRALINE HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 05/09/1999	Stopped: 20/02/2003	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 217845

Seq: 1

Gender: M

Reported: 02/05/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident		Patient experienced a stroke.	

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 217948

Seq: 1

Gender: F

Reported: 03/05/2006

Weight: 0.00

Hospitalisation:

Age: 20

Onset Date:

DOB: 23/04/1986

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperprolactinaemia		Hyperprolactinaemia - this is symptomatic with amenorrhea (no periods).	Medication ceased. Aripiprazole commenced.
Amenorrhoea			
Therapy regimen changed			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 27/12/2004	Stopped: 13/01/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/05/2006	Prolactin	<200.			Prolactin level - 2110.

Additional Information:

Intermittent amenorrhea while on 10mg - worsened on increase to 20mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 217987 **Seq:** 1 **Gender:** F
Reported: 04/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 81
Onset Date: 27/03/2006 **DOB:** 29/06/1924
Outcome: Recovered with sequelae **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypothermia		Hypothermia secondary to antipsychotic treatment (temp 31-33.6 degrees C.	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Batch:	Started:	Stopped:	
SEROQUEL (Suspected)		Reason: Unspecified psychosis	
Tablet	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 06/04/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 217989 is the second sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 218212

Seq: 1

Gender: M

Reported: 10/05/2006

Weight: 70.00

Hospitalisation:

Age: 35

Onset Date: 15/04/2006

DOB: 26/08/1970

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient experienced weight gain of 3 kg in 1 month. Known stable diabetic, developed BSLs of 15 for duration of use of Zyprexa.	Ceased Zyprexa.
Blood glucose increased			

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 31/03/2006	Stopped: 30/04/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 218299 **Seq:** 1 **Gender:** M
Reported: 12/05/2006 **Weight:** 74.00
Hospitalisation: Admitted to hospital **Age:** 62
Onset Date: 24/02/2006 **DOB:** 10/07/1943
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropaenia and leucopenia.	Olanzapine ceased. Treated with GCSF s/c for 5/7.
Leukopenia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OMEPRAZOLE (Other drug)	Reason: Other diseases of esophagus
Batch:	Started: Stopped:
Valganciclovir (Other drug)	Reason: Other prophylactic procedures
Batch:	Started: Stopped:
HALOPERIDOL (Other drug)	Reason: Unspecified psychosis
Batch:	Started: Stopped:
CYCLOSPORIN-A (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
12/05/2006	Lymphocytes				Lymp - 0.43.
12/05/2006	Monocytes				Mono- 0.16.
12/05/2006	Neutrophils				Neut - 0.28.
12/05/2006	White blood cells				WCC - 0.9.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 218299

Seq: 1

Gender: M

Reported: 12/05/2006

Weight: 74.00

Hospitalisation: Admitted to hospital

Age: 62

Onset Date: 24/02/2006

DOB: 10/07/1943

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

LACTULOSE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 17/02/2006	Stopped: 24/02/2006	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 218366
Reported: 15/05/2006

Seq: 1

Gender: F
Weight: 58.00

Hospitalisation:

Onset Date: 20/04/2006

Age: 37

DOB: 16/01/1969

Outcome: Recovered

23/04/2006

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache		Severe headache, dizziness and loss of memory for one and a half hours after patient took medication.	
Dizziness			

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)		Reason: Depression
	50.0 Milligram	Daily Oral
Batch:	Started: L TERM	Stopped:
ZYPREXA (Suspected)		Reason: Depression
Tablet	2.5 Milligram	Daily Oral
Batch:	Started: 20/04/2006	Stopped: 22/04/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 218528

Seq: 1

Gender: M

Reported: 19/05/2006

Weight: 0.00

Hospitalisation:

Age: 51Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Patient developed diabetes, polyuria, polydipsia, nausea and vomiting.	On an unknown date, Olanzapine was discontinued. The pateint's mental condition worsened and therefore Olanzapine was restarted.
Polydipsia			
Polyuria			
Vomiting			

Medicine Details:

AROPAX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
XANAX (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 15/06/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient did not experienced any further problems after restarting Olanzapine. Patient is generally healthy and not overweight.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 218604

Seq: 1

Gender: M

Reported: 23/05/2006

Weight: 0.00

Hospitalisation:

Age: 55Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient developed neuroleptic malignant syndrome.	

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Tablet	7.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 218747

Seq: 1

Gender: M

Reported: 29/05/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose Blood creatine phosphokinase incr Akathisia Delirium		Higher than recommended dose Pateint experienced violent akathisia, delirium and elevated creatine phosphokinase levels.	

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Tablet	45.0 Milligram	Oral	
Batch:	Started:	Stopped:	Continuing.

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/05/2006	Creatine				CPK - >300.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 218832

Seq: 1

Gender: M

Reported: 31/05/2006

Weight: 0.00

Hospitalisation:

Age: 50

Onset Date: 25/05/2006

DOB: 21/04/1956

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Patient developed diabetes.	Reduce the dose of Olanazepine.

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 218879 **Seq:** 1 **Gender:** U
Reported: 02/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 73
Onset Date: **DOB:** 14/12/1932
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cognitive disorder	Caused or prolonged inpatient hospitalisation	13/04/06: Incontinent/Impaired cognition, mobility. 14/04/06: Oedema. 18/04/06: Febrile and dysphagia. 23/04/06: Hyperglycaemia.	Metofrmin, Clomipramine and Ogen ceased.
Dysphagia	Caused or prolonged inpatient hospitalisation		
Hyperglycaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

METFORMIN HYDROCHLORIDE (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started: 25/04/2006	Stopped: 02/05/2006	0
CLOMIPRAMINE HYDROCHLORIDE (Suspected)		Reason:	
Tablet	50.0 Milligram	Daily	Oral
Batch:	Started: 18/11/2005	Stopped: 02/05/2006	
OGEN (Suspected)		Reason:	
	1.3 Milligram	Daily	
Batch:	Started: 16/03/2006	Stopped: 02/05/2006	
ATENOLOL (Suspected)		Reason:	
Tablet	25.0 Milligram	Daily	Oral
Batch:	Started: 26/09/2005	Stopped: 02/05/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 218879 **Seq:** 1 **Gender:** U
Reported: 02/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 73
Onset Date: **DOB:** 14/12/1932
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mobility decreased	Caused or prolonged inpatient hospitalisation		
Oedema	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Explosive personality disorder
	10.0 Milligram Daily	
Batch:	Started: 26/09/2005	Stopped: 02/05/2006 0
EPILIM (Suspected)		Reason: Explosive personality disorder
	1.5 Gram Daily	
Batch:	Started: 26/06/2005	Stopped: 02/05/2006
LASIX (Suspected)		Reason: Edema and dropsy
	80.0 Milligram Daily	
Batch:	Started: 26/09/2005	Stopped: 02/05/2006
ALDACTONE (Suspected)		Reason: Edema and dropsy
Tablet	50.0 Milligram Daily	Oral
Batch:	Started: 26/09/2005	Stopped: 02/05/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 218879 **Seq:** 1

Reported: 02/06/2006

Hospitalisation: Admitted to hospital

Onset Date:

Outcome: Not yet recovered

Gender: U

Weight: 0.00

Age: 73

DOB: 14/12/1932

Causality: Causality possible

Reaction Details:

Medicine Details:

SEROQUEL (Suspected)

Reason: Explosive personality disorder

Tablet

400.0 Milligram

Daily

Oral

Batch:

Started: 26/09/2005

Stopped: 02/05/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 219171
Reported: 15/06/2006

Seq: 1

Gender: M
Weight: 0.00
Age: 15Y

Hospitalisation:

Onset Date: 28/04/2006
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor Dystonia Extrapyramidal disorder Oculogyration Salivary hypersecretion Somnolence		Patient difficult to rouse, shaking, found lying on floor, excess saliva, EPSE, open eyes rolling back, tuncal dystonia, gait, tongue.	Given Benztropine imi/oral.

Medicine Details:

DIAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec
2.5 Milligram	
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	
Batch:	Started: Stopped:
DIAZEPAM (Other drug)	Reason:
5.0 Milligram	
Batch:	Started: 14/04/2006 Stopped:
CLOPIXOL-ACUPHASE (Suspected)	Reason:
Injection	100.0 Milligram 1 time Intramuscular
Batch:	Started: 28/04/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 219171

Seq: 1

Gender: M

Reported: 15/06/2006

Weight: 0.00

Hospitalisation:

Age: 15Y

Onset Date: 28/04/2006

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)

Reason: Otr spec symp psychopathol nec

5.0 Milligram

As necessary

Batch:

Started: 11/04/2006

Stopped:

0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 219524

Seq: 1

Gender: F

Reported: 27/06/2006

Weight: 0.00

Hospitalisation:

Age: 24Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Patient was placed on Olanzapine and put on a fair amount of weight.	Olanzapine was ceased and her Lithium dose was increased to 500mg twice a day.

Medicine Details:

OLANZAPINE (Suspected)	Reason: Depression
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 219520 is the first sequence to this report 219521 is the second sequence and 219525 is the fourth sequence.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 219754

Seq: 1

Gender: M

Reported: 06/07/2006

Weight: 78.00

Hospitalisation:

Onset Date: 25/05/2006

Age: 48Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash		Patient experienced rash widespread over legs, arm, trunk, groin, back.	Ceased Zyprexa and changed to Quetiapine, treated with Phenergan.

Medicine Details:

PANAMAX (Other drug)	Reason:
Batch:	Started: Stopped:
PRAMIN (Other drug)	Reason:
Batch:	Started: Stopped:
ZOFRAN (Other drug)	Reason:
Batch:	Started: Stopped:
MORPHINE SULPHATE (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 219754

Seq: 1

Gender: M

Reported: 06/07/2006

Weight: 78.00

Hospitalisation:

Age: 48Y

Onset Date: 25/05/2006

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLEXANE (Other drug)		Reason:
Batch:	Started:	Stopped:
CARDIPRIN 100 (Other drug)		Reason:
Batch:	Started:	Stopped:
NIMOTOP (Other drug)		Reason:
Batch:	Started:	Stopped:
COLOXYL WITH SENNA (Other drug)		Reason:
Batch:	Started:	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 219754

Seq: 1

Gender: M

Reported: 06/07/2006

Weight: 78.00

Hospitalisation:

Age: 48Y

Onset Date: 25/05/2006

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

LACTULOSE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
PANADEINE FORTE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Zyprexa Zydis (Suspected)		Reason: Explosive personality disorder	
Wafer	5.0 Milligram	As necessary	Oral
Batch:	Started: 24/05/2006	Stopped: 25/05/2006	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 219778 **Seq:** 1 **Gender:** M
Reported: 06/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 44Y
Onset Date: 17/03/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient collapsed and fited after a very long walk on hot day, temp 42.5 and neuroleptic malignant syndrome suspected.	Intubated, fluid resuscitation, ICU management including haemofiltration. Only Phenytoin and BZ used for seizures (no antipsychotics yet).
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PHENYTOIN SODIUM (Other drug)		Reason:
	200.0 Milligram	
Batch:	Started:	Stopped:
METOPROLOL TARTRATE (Other drug)		Reason:
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
	10.0 Milligram Daily	
Batch:	Started:	Stopped: 14/03/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/07/2006	Creatine				Peak CK - 27,000.
06/07/2006	Potassium				K+ - 7.0.

Additional Information:

NMS developed when patient was very dehydrated. Pineal breain tumour (age 20). Eleven operations for this. Secondary epilepsy and ventricular flow disturbance has VP shunt.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 219778 **Seq:** 1 **Gender:** M
Reported: 06/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 44Y
Onset Date: 17/03/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation		
Convulsion	Caused or prolonged inpatient hospitalisation		
Hyperkalaemia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PHENYTOIN SODIUM (Other drug)		Reason:
	200.0 Milligram	
Batch:	Started:	Stopped:
METOPROLOL TARTRATE (Other drug)		Reason:
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
	10.0 Milligram Daily	
Batch:	Started:	Stopped: 14/03/2006

Laboratory Investigations:

Additional Information:

NMS developed when patient was very dehydrated. Pineal brain tumour (age 20). Eleven operations for this. Secondary epilepsy and ventricular flow disturbance has VP shunt.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 219778 **Seq:** 1 **Gender:** M
Reported: 06/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 44Y
Onset Date: 17/03/2006 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Renal failure acute	Caused or prolonged inpatient hospitalisation		

Medicine Details:

PHENYTOIN SODIUM (Other drug)		Reason:
	200.0 Milligram	
Batch:	Started:	Stopped:
METOPROLOL TARTRATE (Other drug)		Reason:
Batch:	Started:	Stopped:
OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia
	10.0 Milligram Daily	
Batch:	Started:	Stopped: 14/03/2006

Laboratory Investigations:

Additional Information:

NMS developed when patient was very dehydrated. Pineal brain tumour (age 20). Eleven operations for this. Secondary epilepsy and ventricular flow disturbance has VP shunt.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 219827

Seq: 1

Gender: F

Reported: 10/07/2006

Weight: 0.00

Hospitalisation:

Onset Date: 01/09/2005

Age: 25Y

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion		Patient experienced fetal anomalies, cystic hygroma, pericardial effusion, oligohydramnios, left kidney dilation, absent right kidney. Neonatal death 01/09/2005.	
Death neonatal			
Oligohydramnios			
Renal aplasia			

Medicine Details:

Amphetamine (Suspected)		Reason:	
Injection	2.0	Dose Unspecified Weekly	Intravenous
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	10.0	Milligram Daily	
Batch:	Started:	Stopped:	
CANNABIS PREPARATION (Suspected)		Reason:	
		Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220030
Reported: 14/07/2006

Seq: 1

Gender: M
Weight: 0.00
Age: 79Y

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Skin reaction		Irritating skin reaction.	Zyprexa and Tolvon ceased. Given salt tablets 1800mg/bd.

Medicine Details:

DEPTRAN (Other drug)		Reason:	
	50.0 Milligram		Oral
Batch:	Started:	Stopped:	
NORMISON (Other drug)		Reason:	
	10.0 Milligram		Oral
Batch:	Started:	Stopped:	
LIPITOR (Other drug)		Reason:	
Tablet	10.0 Milligram		Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason:	
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/07/2006	Sodium		04/04/2006	137	
14/07/2006	Sodium		11/04/2006	134	
14/07/2006	Sodium		18/04/2006	133	
14/07/2006	Sodium		26/04/2006	129	
14/07/2006	Sodium		14/06/2006	136	
14/07/2006	Sodium		28/06/2006	136	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220030

Seq: 1

Gender: M

Reported: 14/07/2006

Weight: 0.00

Hospitalisation:

Age: 79Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

TOLVON (Suspected)

Reason:

Tablet

40.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 220234

Seq: 1

Gender: F

Reported: 20/07/2006

Weight: 70.00

Hospitalisation:

Age: 43Y

Onset Date: 15/12/2005

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Breast cancer female		Patient developed breast cancer.	Received treatment (unspecified).

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/08/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220379
Reported: 26/07/2006

Seq: 1

Gender: M

Weight: 68.00

Hospitalisation:

Onset Date: 19/07/2006

Age: 48

DOB: 10/12/1957

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Incapacity/disability	Had been on valproate (Epilim) 500mg bd until mid-June; this was reinstated on admission, and the dose escalated to 500mg mane/1000mg nocte on 13 July.	

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	
	45.0 Milligram		
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Suspected)		Reason: Unspecified neurosis	
Tablet	1.5 Gram	Alternating-other	Oral
Batch: unknown	Started: 12/07/2006	Stopped: 20/07/2006	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/07/2006	Other data				Investigations revealed normal FBC, EUC and LFT, but the valproate level (992 micromol/L, 5h post mane dose) and ammonia level (195 micromol/L) were elevated on 20 July.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220379
Reported: 26/07/2006

Seq: 1

Gender: M

Weight: 68.00

Hospitalisation:

Onset Date: 19/07/2006

Age: 48

DOB: 10/12/1957

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Musculoskeletal stiffness	Incapacity/disability	subjectively restless, panicky, stiff and shaky, and was observed to have bradykinesia, parkinsonian gait (but normal muscle tone), confusion, mild upper limb ataxia (clumsiness handling dinner plate etc) and a slight flap/tremor. valproate level (992 micromol/L, 5h post mane dose) and ammonia level (195 micromol/L) were elevated on 20 July. Patient was exquisitely sensitive to 5mg diazepam stat dose on 19 July.	Patient was exquisitely sensitive to 5mg diazepam stat dose on 19 July., Valproate was ceased immediately on clinical suspicion and olanzapine reduced to 7.5mg. Carnitine supplementation to be commenced when available, after repeat blood sample for valproate/carnitine levels.
Ammonia increased	Incapacity/disability		

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	
	45.0 Milligram		
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Suspected)		Reason: Unspecified neurosis	
Tablet	1.5 Gram	Alternating-other	Oral
Batch: unknown	Started: 12/07/2006	Stopped: 20/07/2006	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220379
Reported: 26/07/2006

Seq: 1

Gender: M
Weight: 68.00
Age: 48
DOB: 10/12/1957
Causality: Causality possible

Hospitalisation:

Onset Date: 19/07/2006
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Asterixis	Incapacity/disability		
Bradykinesia	Incapacity/disability		
Confusional state	Incapacity/disability		
Coordination abnormal	Incapacity/disability		
Drug level above therapeutic	Incapacity/disability		
Panic attack	Incapacity/disability		

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	
	45.0 Milligram		
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Suspected)		Reason: Unspecified neurosis	
Tablet	1.5 Gram	Alternating-other	Oral
Batch: unknown	Started: 12/07/2006	Stopped: 20/07/2006	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 220379
Reported: 26/07/2006

Seq: 1

Gender: M
Weight: 68.00
Age: 48
DOB: 10/12/1957
Causality: Causality possible

Hospitalisation:

Onset Date: 19/07/2006
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonian gait	Incapacity/disability		
Restlessness	Incapacity/disability		
Tremor	Incapacity/disability		

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	
	45.0 Milligram		
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
	10.0 Milligram		
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Suspected)		Reason: Unspecified neurosis	
Tablet	1.5 Gram	Alternating-other	Oral
Batch: unknown	Started: 12/07/2006	Stopped: 20/07/2006	0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 220675 **Seq:** 1 **Gender:** F
Reported: 09/08/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 13Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus	Caused or prolonged inpatient hospitalisation	Weight gain of 45 kg over a period of six months while on olanzapine treatment, after the weight gain patient became diabetic. Zyprexa takes every feeling away from the patient, has had serious behavioural problems for many years. Worsening of violent outbursts.	
Abnormal behaviour	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 220675 **Seq:** 1 **Gender:** F
Reported: 09/08/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 13Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation		
Flat affect	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220741 **Seq:** 1 **Gender:** M
Reported: 11/08/2006 **Weight:** 80.00
Hospitalisation: Required a visit to the doctor **Age:** 32
Onset Date: 17/07/2006 **DOB:** 22/04/1974
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gynaecomastia		Gynaecomastia-swollen areolae, enlarged breast tissue, hyper prolactinaemia - increased to 84. (0-372) on the 18/7/06. Tender nipples.	Stopped Olanzapine, switched to quetiapine.
Hyperprolactinaemia			
Nipple pain			

Medicine Details:

SODIUM VALPROATE (Other drug)		Reason: Manic-depression psycho,manic
	2.0 Gram	
Batch:	Started: 08/06/2006	Stopped:
METHADONE HYDROCHLORIDE (Other drug)		Reason:
	50.0 Milligram	
Batch:	Started: 26/05/2006	Stopped:
OLANZAPINE (Suspected)		Reason: Manic-depression psycho,manic
Tablet	30.0 Milligram	Daily Oral
Batch:	Started: 01/05/2006	Stopped: 18/07/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220779

Seq: 1

Gender: F

Reported: 14/08/2006

Weight: 0.00

Hospitalisation:

Age: 19Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain of 35kg.	Exercising.

Medicine Details:

RISPERIDONE (Other drug)	Reason:
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 220779

Seq: 1

Gender: F

Reported: 14/08/2006

Weight: 0.00

Hospitalisation:

Age: 19Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

ZYPREXA (Suspected)

Reason: Unspecifid affective psychosis

15.0 Milligram

Daily

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 220962
Reported: 23/08/2006

Seq: 1

Gender: U
Weight: 0.00
Age: 99u

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cleft palate	Congenital anomaly / birth defect	Infant born with small cleft palate.	

Medicine Details:

LITHIUM CARBONATE (Suspected)		Reason: Depression	
Tablet	900.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Depression	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
LAMOTRIGINE (Suspected)		Reason: Depression	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EFEXOR-XR (Suspected)		Reason: Depression	
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Female baby born on 05/06/06.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221110 **Seq:** 1 **Gender:** M
Reported: 28/08/2006 **Weight:** 85.00
Hospitalisation: Required a visit to the doctor **Age:** 34
Onset Date: 01/03/2006 **DOB:** 03/05/1971
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swelling Dyspepsia Vomiting Weight increased		Foot swelling, heartburn, 3 episodes of vomiting at night and 5kg weight gain.	olanzapine and methadone ceased.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	10.0 Milligram	Daily	
Batch:	Started: 22/02/2006	Stopped: 01/08/2006	
METHADONE HYDROCHLORIDE (Suspected)		Reason:	
Oral Liquid	50.0 Millilitre	Daily	Oral
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221190
Reported: 29/08/2006

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 15/05/2006

Age: 13

DOB: 23/04/1993

Outcome: Recovered

15/08/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Increased weight - very fast increase in weight (30 to 40kg in 3 months) and blood sugar level increased.	Olanzapine and Sodium Valproate stopped. Patient required insulin.
Blood glucose increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
	15.0 Milligram	Daily	
Batch:	Started: 31/03/2006	Stopped: 17/07/2006	
SODIUM VALPROATE (Suspected)		Reason:	
	1.0 Gram	Daily	
Batch:	Started:	Stopped: 26/07/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221283

Seq: 1

Gender: F

Reported: 01/09/2006

Weight: 0.00

Hospitalisation:

Onset Date: 03/08/2006

Age: 70Y

Outcome: Not yet recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Caused or prolonged inpatient hospitalisation	Acute myocardial infarction.	

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
OXAZEPAM (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Depression	
	5.0 Milligram	Daily	Oral
Batch:	Started: 02/08/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221284
Reported: 01/09/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	Hypotensive crisis and then subsequently "passed out". ECG showed a mixed low pulse.	Zyprexa Zydis ceased.
Heart rate decreased	Caused or prolonged inpatient hospitalisation		
Heart rate irregular	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Zyprexa Zydis (Suspected)		Reason: Unspecified psychosis	
Wafer	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical history included amphetamine induced psychosis and a mild congenital abnormality of mixed/low pulse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 221284

Seq: 1

Gender: M

Reported: 01/09/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLONAZEPAM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Zyprexa Zydys (Suspected)		Reason: Unspecified psychosis	
Wafer	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Medical history included amphetamine induced psychosis and a mild congenital abnormality of mixed/low pulse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221486

Seq: 1

Gender: U

Reported: 07/09/2006

Weight: 62.00

Hospitalisation:

Age: 17

Onset Date: 04/08/2006

DOB: 09/08/1988

Outcome: Recovered

04/08/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Seizure: Grand mal seizure, tonic clonic x 2 in the space of 4-6 hours.	Supporting therapy, IVT, Neuro Obs.
Grand mal convulsion			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	
Batch:	Started: 20/07/2006	Stopped: 05/08/2006	
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason: Depression	
	40.0 Milligram	Daily	
Batch:	Started: 15/07/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221565
Reported: 12/09/2006

Seq: 1

Gender: F
Weight: 0.00
Age: 32Y

Hospitalisation:

Onset Date: 06/05/2006
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Intentional overdose	Caused or prolonged inpatient hospitalisation	took 273 x75mg capsules of efexor-xr, and experienced vertigo, fever, vomiting, 5 grand mal seizures, tachycardia, discomfort nausea, asthenia, palpitations, rhabdomyolysis, acute renal insufficiency and rased creatinine levels	
Suicide attempt	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ALCOHOL (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
ZYPREXA (Suspected)		Reason:	
Batch:	Started:	Stopped:	0
EFEXOR-XR (Suspected)		Reason:	
Capsule	20.0 Gram	Total	Oral
Batch:	Started: 06/05/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221605

Seq: 1

Gender: F

Reported: 13/09/2006

Weight: 0.00

Hospitalisation:

Age: 61

Onset Date: 23/08/2006

DOB: 31/07/1945

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Abnormal LFT's and severe EPSE.	Withdrew promethazine, Lipitor, olanzapine and risperidone. Small doses benztropine prn.
Extrapyramidal disorder			

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:
ALENDRONATE SODIUM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221605

Seq: 1

Gender: F

Reported: 13/09/2006

Weight: 0.00

Hospitalisation:

Onset Date: 23/08/2006

Age: 61

Outcome: Not yet recovered

DOB: 31/07/1945

Causality: Causality possible

Reaction Details:

Medicine Details:

LIPITOR (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
PROMETHAZINE HYDROCHLORIDE (Suspected)		Reason:	
	25.0 Milligram	As necessary	Oral
Batch:	Started:	S TERM	Stopped:
RISPERIDONE (Suspected)		Reason:	
	1.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:
OLANZAPINE (Suspected)		Reason:	
	15.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 221836

Seq: 1

Gender: F

Reported: 25/09/2006

Weight: 0.00

Hospitalisation:

Age: 55Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Angioedema			

Medicine Details:

VENLAFAXINE HYDROCHLORIDE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason: Depression	
	2.5 Milligram	Daily	
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 222168 **Seq:** 1 **Gender:** M
Reported: 05/10/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 26Y
Onset Date: 13/08/2006 **DOB:**
Outcome: Recovered 14/08/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicide attempt	Caused or prolonged inpatient hospitalisation	Admitted after a suicide attempt in which he took 90 or so anti-schizophrenia tablets with alcohol.	
Alcoholism	Caused or prolonged inpatient hospitalisation		
Depression	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Medical condition: Suicide attempt and self mutilation.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 222168 **Seq:** 1 **Gender:** M
Reported: 05/10/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 26Y
Onset Date: 13/08/2006 **DOB:**
Outcome: Recovered 14/08/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug dependence	Caused or prolonged inpatient hospitalisation		
Self mutilation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecified psychosis
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Medical condition: Suicide attempt and self mutilation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 222843

Seq: 1

Gender: M

Reported: 01/11/2006

Weight: 0.00

Hospitalisation:

Age: 31Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal behaviour		Neuroleptic Malignant Syndrome because his sone has excessive salivation, suicidal, homicidal, akathisia, extrapyramidal symptoms and hives, although GP stated it is acne.	
Acne			
Akathisia			
Extrapyramidal disorder			
Homicidal ideation			
Salivary hypersecretion			
Urticaria			

Medicine Details:

AMISULPRIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Zyprexa IM (Suspected)		Reason: Unspecified schizophrenia	
Injection	10.0 Milligram	As necessary	Intramuscular
Batch:	Started:	Stopped: 0	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
	60.0 Milligram	Daily	Oral
Batch:	Started: L TERM	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 223047

Seq: 1

Gender: M

Reported: 13/11/2006

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date:

DOB: 27/06/1984

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Suicidal ideation Homicidal ideation		Suicidal ideation, homicidal ideation.	

Medicine Details:

LITHIUM CARBONATE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Strattera (Suspected)		Reason: Behavior disorders of childhood	
	10.0 Milligram		
Batch:	Started:	Stopped: 0	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
	5.0 Milligram Daily		
Batch:	Started:	Stopped: 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Other relevant history suicide attempt.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 223069

Seq: 1

Gender: F

Reported: 13/11/2006

Weight: 0.00

Hospitalisation:

Age: 68Y

Onset Date:

DOB:

Outcome: Death

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Death	Patient experienced a stroke and died.	

Medicine Details:

ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 223705

Seq: 1

Gender: M

Reported: 01/12/2006

Weight: 0.00

Hospitalisation:

Onset Date: 24/10/2006

Age: 25

DOB: 12/10/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increase		Patient had increased Alanine aminotransferase, aspartate amino-transferase and gamma glutamyltransferase.	Olanzapine was stopped and clozapine withheld, Recommended next day and increased slowly with improvement of liver function
Aspartate aminotransferase increase			
Gamma-glutamyltransferase increase			

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 10/10/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2006	ALT = SGPT	<55	23/10/2006	354	baseline: 90
01/12/2006	ALT = SGPT	<55	24/10/2006	306	baseline: 90
01/12/2006	ALT = SGPT	<55	26/10/2006	239	baseline: 90
01/12/2006	ALT = SGPT	<55	29/10/2006	143	baseline: 90
01/12/2006	ALT = SGPT	<55	03/10/2006	105	baseline: 90
01/12/2006	ALT = SGPT	<55	31/10/2006	90	baseline: 90
01/12/2006	AST = SGOT	<50	23/10/2006	153	Baseline: normal

Additional Information:

Patient has hepatitis B.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 223705
Reported: 01/12/2006

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 24/10/2006

Age: 25

DOB: 12/10/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 10/10/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2006	AST = SGOT	<50	24/10/2006	85	Baseline: normal
01/12/2006	AST = SGOT	<50	26/10/2006	66	Baseline: normal
01/12/2006	Bilirubin	<19	03/10/2006	20	
01/12/2006	Bilirubin	<19	26/10/2006	19	
01/12/2006	GGT = SGGT =	<50	23/10/2006	192	baseline: 90
01/12/2006	GGT = SGGT =	<50	24/10/2006	181	baseline: 90
01/12/2006	GGT = SGGT =	<50	26/10/2006	161	baseline: 90

Additional Information:

Patient has hepatitis B.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 223705

Seq: 1

Gender: M

Reported: 01/12/2006

Weight: 0.00

Hospitalisation:

Age: 25

Onset Date: 24/10/2006

DOB: 12/10/1981

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)		Reason:	
Tablet	12.5 Milligram	Daily	Oral
Batch:	Started: 10/10/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
01/12/2006	GGT = SGGT =	<50	31/10/2006	132	baseline: 90
01/12/2006	GGT = SGGT =	<50	03/10/2006	119	baseline: 90
01/12/2006	Ultrasound				24 Oct: fatty liver

Additional Information:

Patient has hepatitis B.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224127
Reported: 15/12/2006

Seq: 1

Gender: M

Weight: 49.00

Hospitalisation:

Onset Date: 09/12/2006

Age: 13

DOB: 27/12/1992

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		acute dystonic reaction	Benztropine 2mg IM and then regular benztropine 1mg orally since as well as reduction in dose

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	1 time	Oral
Batch:	Started: 20/11/2006	Stopped: 08/12/2006	0
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Tablet	4.0 Milligram	Daily	Oral
Batch:	Started: 07/12/2006	Stopped: 09/12/2006	0
RISPERIDONE (Suspected)		Reason: Unspecified psychosis	
Injection	25.0 Milligram	Alternate weeks	Intramuscular
Batch:	Started: 08/12/2006	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
15/12/2006	Other data				genetic testing for CYP2D6 phenotyping maybe done

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224128 **Seq:** 1 **Gender:** M
Reported: 15/12/2006 **Weight:** 69.00
Hospitalisation: Required a visit to the doctor **Age:** 27Y
Onset Date: **DOB:**
Outcome: Recovered 01/09/2006 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Polydipsia		Experiencing extreme thirst and drinking 9-10 L fluid daily	
Polyuria	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
EDRONAX (Suspected)		Reason: Depression	
Tablet	12.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224162
Reported: 18/12/2006

Seq: 1

Gender: M
Weight: 0.00
Age: 46Y

Hospitalisation:

Onset Date: 05/10/2006
Outcome: Recovered

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pulmonary oedema	Caused or prolonged inpatient hospitalisation	Pulmonary oedema, facial oedema, peripheral oedema, generalised oedema.	IV Frusemide
Face oedema	Caused or prolonged inpatient hospitalisation		
Generalised oedema	Caused or prolonged inpatient hospitalisation		

Medicine Details:

AROPAX (Other drug)	Reason:
Batch:	Started: Stopped:
METHADONE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
INDOMETHACIN (Other drug)	Reason:
Batch:	Started: Stopped:
TEMAZEPAM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 224162

Seq: 1

Gender: M

Reported: 18/12/2006

Weight: 0.00

Hospitalisation:

Age: 46Y

Onset Date: 05/10/2006

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
Tablet	2.5 Milligram Daily Oral
Batch:	Started: 01/10/2006 Stopped: 07/10/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 224163

Seq: 1

Gender: M

Reported: 18/12/2006

Weight: 0.00

Hospitalisation:

Age: 40Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardyomyopthay.	

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 224400

Seq: 1

Gender: F

Reported: 05/01/2007

Weight: 60.00

Hospitalisation:

Age: 77

Onset Date: 05/12/2006

DOB: 10/10/1929

Outcome: Recovered

07/12/2006

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Life threatening	Neuroleptic Malignant Syndrome	Supportive

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Tablet	5.0 Milligram	Daily	Oral
Batch:	Started: 30/11/2006	Stopped: 06/12/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 224483 **Seq:** 1 **Gender:** F
Reported: 09/01/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	Patient experienced a psychotic episode.	Drug discontinued.

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient's medical history included depression and had taken antidepressant.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224526 **Seq:** 1 **Gender:** M
Reported: 10/01/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 39
Onset Date: 24/09/2006 **DOB:** 12/12/1966
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Photosensitivity reaction		Photo sensitive reaction, rash on foot exposed parts.	Ceased Zyprexa
Rash			

Medicine Details:

SEROQUEL (Other drug)	Reason: Unspecified schizophrenia
600.0 Milligram	
Batch:	Started: Stopped:
Valpam (Other drug)	Reason:
30.0 Milligram	
Batch:	Started: Stopped:
FUNGILIN (Other drug)	Reason:
Lozenge	3.0 Dose Unspecified Oral
Batch:	Started: Stopped:
COGENTIN (Other drug)	Reason:
4.0 Milligram	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224526

Seq: 1

Gender: M

Reported: 10/01/2007

Weight: 0.00

Hospitalisation: Required a visit to the doctor

Age: 39

Onset Date: 24/09/2006

DOB: 12/12/1966

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPIXOL DEPOT (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224568

Seq: 1

Gender: F

Reported: 10/01/2007

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Weight gain,	

Medicine Details:

RISPERIDONE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecified psychosis	
Batch:	Started:	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The reporting psychiatrist was concerned that the patient's obesity may be affecting her absorption, as the patient still had some psychotic symptoms. He was also concerned about drug efficacy due to the stomach banding.
Procedure Gastric banding.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224569

Seq: 1

Gender: F

Reported: 10/01/2007

Weight: 0.00

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gamma-glutamyltransferase increa		Gamma- glutamyltransferase increased.	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 224715 **Seq:** 1 **Gender:** M
Reported: 16/01/2007 **Weight:** 76.00
Hospitalisation: Required a visit to the doctor **Age:** 22
Onset Date: 09/10/2006 **DOB:** 02/02/1984
Outcome: Recovered 31/10/2006 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Asymptomatic neutropenia.	Cessation of drug.

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 14/09/2006	Stopped: 27/10/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/01/2007	Neutrophils		09/10/2006	1.7	
16/01/2007	Neutrophils		12/10/2006	1.9	
16/01/2007	Neutrophils		23/10/2006	1.7	
16/01/2007	Neutrophils		31/10/2006	5.0	

Additional Information:

Suspected cause-olanzapine previous neutropenia on clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224770

Seq: 1

Gender: M

Reported: 17/01/2007

Weight: 85.00

Hospitalisation:

Age: 36

Onset Date: 05/12/2006

DOB: 17/11/1970

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia, Asymptomatic.	

Medicine Details:

MIRTAZAPINE (Suspected)		Reason:	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 29/11/2006	Stopped: 02/12/2006	
OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
	5.0 Milligram	Daily	
Batch:	Started: 02/12/2006	Stopped: 06/12/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/01/2007	Neutrophils				Neutrophils 1.0.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 224836

Seq: 1

Gender: F

Reported: 18/01/2007

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 18Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation	Patient not chewing or swallowing, experiencing increased saliva and drooling.	Tetrabenazine was initiated.
Drooling	Caused or prolonged inpatient hospitalisation		

Medicine Details:

OLANZAPINE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Yet to exclude other causes such as bulber nerve problem.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 224876

Seq: 1

Gender: F

Reported: 19/01/2007

Weight: 0.00

Hospitalisation:

Age: 18Y

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphagia	Caused or prolonged inpatient hospitalisation	Patient had trouble swallowing and chewing.	Drug discontinued, started Escitalopram oxalate
Mastication disorder	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

RISPERDAL (Suspected)		Reason:	
Batch:	Started:	Stopped: 08/12/2006	
TETRABENAZINE (Suspected)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Other atyp forms schizophrenia	
Tablet	7.5 Milligram	Daily	Oral
Batch:	Started: 01/08/2006	Stopped: 07/12/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225026

Seq: 1

Gender: F

Reported: 24/01/2007

Weight: 62.00

Hospitalisation:

Age: 18

Onset Date: 29/12/2006

DOB: 06/02/1988

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus Acidosis Diabetes mellitus insulin-dependen		Acute onset Diabetes with Keto Acidosis	Insulin

Medicine Details:

ZYPREXA (Suspected)	Reason:		
Tablet	2.5 Milligram	Daily	Oral
Batch:	Started: 15/06/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
24/01/2007	Other data				Urine Ketones
24/01/2007	Serum glucose				

Additional Information:

History: relatives diabetes. BSL fasting normal in June before starting olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225326 **Seq:** 1 **Gender:** M
Reported: 02/02/2007 **Weight:** 80.00
Hospitalisation: Required a visit to the doctor **Age:** 40
Onset Date: 27/12/2006 **DOB:** 24/07/1966
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tremor Akathisia Parkinsonism		Severe extra pyramidal side effects. Tremor, Parkinsonian appearance, Akathisia.	Reduce olanzapine to 10mg, Benztropine.

Medicine Details:

OLANZAPINE (Suspected)	Reason: Othr&unspec metabolic diseases
20.0 Milligram	Daily
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225541
Reported: 07/02/2007

Seq: 1

Gender: M
Weight: 85.00

Hospitalisation:

Onset Date: 21/12/2006

Age: 31

DOB: 20/07/1975

Outcome: Recovered

07/01/2007

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		Patient with normal baseline LFT's. Commenced Olanzapine, titrated to 10mg tds, after 3 weeks, LFTs - in particular. ALT high 21 to 395. All other LFT's remained in normal range.	

Medicine Details:

LITHIUM CARBONATE (Other drug)	Reason:
900.0 Milligram	
Batch:	Started: 30/11/2006 Stopped:
ATIVAN (Other drug)	Reason: Otr spec symp psychopathol nec
1.5 Milligram	Daily
Batch:	Started: 30/11/2006 Stopped:
ZYPREXA (Suspected)	Reason: Unspecified psychosis
30.0 Milligram	Daily
Batch:	Started: 30/11/2006 Stopped: 21/12/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
07/02/2007	ALT = SGPT				ALT up from 21 to 395
07/02/2007	GGT = SGGT =				GGT up from 13 to 84

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225583

Seq: 1

Gender: M

Reported: 08/02/2007

Weight: 107.00

Hospitalisation:

Onset Date: 19/11/2006

Age: 38Y

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe	Caused or prolonged inpatient hospitalisation	New onset Type 2 diabetes.	Metformin

Medicine Details:

DIAZEPAM (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped:	
Lexapro (Other drug)		Reason: Unspecifid affective psychosis	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/02/2007	Other data		19/11/2006	7.5	HBAIC
08/02/2007	Serum glucose		19/11/2006	16.7	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 225647

Seq: 1

Gender: F

Reported: 08/02/2007

Weight: 0.00

Hospitalisation:

Age: 34

Onset Date:

DOB: 29/07/1972

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Ovarian cyst		Orarian cyst.	

Medicine Details:

OLANZAPINE (Suspected)		Reason: Unspecified psychosis	
Batch:	Started:	L TERM	Stopped: 15/04/2001

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225725
Reported: 12/02/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date: 04/12/2006

Age: 22

DOB: 31/08/1984

Outcome: Recovered

08/12/2006

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Patient experienced weight gain and severe sedation.	Clopine withdrawn. Patient intubated and remained in ICU.
Sedation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Escitalopram (Other drug)	Reason:
20.0 Milligram	
Batch:	Started: Stopped:
FLUOXETINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
Metoprolol Succinate (Other drug)	Reason:
Batch:	Started: Stopped:
ALPRAZOLAM (Suspected)	Reason: Anxiety neurosis
Tablet	Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has a history of obesity, alcohol abuse, benzodiazepine abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 225725

Seq: 1

Gender: M

Reported: 12/02/2007

Weight: 0.00

Hospitalisation:

Age: 22

Onset Date: 04/12/2006

DOB: 31/08/1984

Outcome: Recovered

08/12/2006

Causality: Causality possible

Reaction Details:

Medicine Details:

CLOPINE (Suspected)

Reason: Unspecified psychosis

Tablet

300.0 Milligram

Daily

Oral

Batch:

Started: 05/10/2006

Stopped: 12/12/2006

OLANZAPINE (Suspected)

Reason: Unspecified psychosis

Tablet

20.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:

The patient has a history of obesity, alcohol abuse, benzodiazepine abuse.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 225884

Seq: 1

Gender: M

Reported: 15/02/2007

Weight: 0.00

Hospitalisation:

Age: 35Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neutrophilia	Caused or prolonged inpatient hospitalisation	12 months after commencement of olanzapine, patient experienced neutrophilia.	Olanzapine discontinued.

Medicine Details:

ZYPREXA (Suspected)	Reason:		
	10.0	Milligram	Daily
Batch:	Started:	L TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 226279

Seq: 1

Gender: M

Reported: 04/03/2007

Weight: 75.00

Hospitalisation:

Age: 32Y

Onset Date: 15/01/2007

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Hyperglycaemia BSL 15.6	Cease medication

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/03/2007	Biochemistry				BSL 15.6mmol/L

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames: OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 226294

Seq: 1

Gender: F

Reported: 05/03/2007

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		doctor suspected abdominal distension was due to fluid retention, rapid weight gain of 9 kilograms	
Abdominal distension			

Medicine Details:

SEROQUEL (Suspected)				Reason:	
Batch:		Started:		Stopped:	
OLANZAPINE (Suspected)				Reason:	
Batch:		Started:		Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Abdominal distension and weight gain occurred after one week of olanzapine treatment, and worsened on commencement of Seroquel, switched to risperidone but developed "prolactin issues" and then switched to aripiprazole



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 226448

Seq: 1

Gender: M

Reported: 07/03/2007

Weight: 0.00

Hospitalisation:

Onset Date: 15/02/2007

Age: 67

DOB: 03/09/1939

Outcome: Unknown

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient's weight increased by 10 kilograms over 8 weeks while on Olanzapine treatment.	

Medicine Details:

COUMADIN (Other drug)		Reason:	
Batch:	Started:	Stopped:	
METFORMIN HYDROCHLORIDE (Other drug)		Reason:	
Batch:	Started:	Stopped:	
DIAMICRON (Other drug)		Reason:	
Batch:	Started:	Stopped:	
ZYPREXA (Suspected)		Reason: Unspecifid affective psychosis	
	5.0 Milligram		
Batch:	Started: 15/12/2006	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 226589

Seq: 1

Gender: F

Reported: 13/03/2007

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Renal failure		Renal failure	Ceased olanzapine

Medicine Details:

OLANZAPINE (Suspected)

Reason: Unspecified schizophrenia

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 226590

Seq: 1

Gender: F

Reported: 13/03/2007

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nephritis interstitial		Nephritis interstitial suspected.	Olanzapine discontinued.

Medicine Details:

OLANZAPINE (Suspected)

Reason: Unspecified schizophrenia

Batch:

Started:

Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 226604

Seq: 1

Gender: M

Reported: 09/03/2007

Weight: 92.00

Hospitalisation:

Age: 28

Onset Date:

DOB: 22/11/1978

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pruritus		Itchy rash on arms, legs, palms of hands ,fine macular rash on trunk and limbs-large hives, has persisted for approx 2 months.	
Rash generalised			
Rash macular			
Urticaria			

Medicine Details:

OLANZAPINE (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 05/07/2006	Stopped: 05/01/2007	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No other obvious allergies.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 226868
Reported: 22/03/2007

Seq: 1

Gender: M
Weight: 0.00
Age: 21Y

Hospitalisation:

Onset Date: 20/02/2007
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation Catatonia Drug ineffective Headache Therapy regimen changed		Sedation, catatonia, headache, medication dose increased - Zyprexa 5mg to 10mg daily (19/02/07) and drug ineffective. "It worked well the first day" but "the medication dis not seem to work" on the second day.	

Medicine Details:

EPILIM (Other drug)		Reason:	
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:	
Tablet		Oral	
Batch:	Started:	Stopped:	
TEGRETOL CR (Suspected)		Reason:	
Tablet	200.0 Milligram	Daily	Oral
Batch:	Started: 19/02/2007	Stopped:	
ZYPREXA (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started:	Stopped: 18/02/2007	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Schizophrenia and bipolar disorder. The reporter believed that the return of catatonia was due to the increased dose of Zyprexa the day before, "which normally increased his catatonia".



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 226921

Seq: 1

Gender: F

Reported: 23/03/2007

Weight: 0.00

Hospitalisation:

Onset Date: 18/11/2006

Age: 26Y

Outcome: Unknown

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gravitational oedema		Fluid retention in ankles, including pain, especially when weight bearing.	Treated with frusemide, given as stat pm doses - not a regular order, TED stockings.

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)		Reason:	
30.0 Milligram			
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Other drug)		Reason:	
450.0 Milligram			
Batch:	Started:	Stopped:	
OLANZAPINE (Suspected)		Reason:	
20.0 Milligram		Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 226934
Reported: 23/03/2007

Seq: 1

Gender: M

Weight: 0.00

Hospitalisation:

Onset Date:

Age: 56

Outcome: Unknown

DOB: 15/09/1950

Causality: Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus non-insulin-depe Hyperglycaemia Syncope		The patient received olanzapine 2.5mg daily and experienced elevated blood glucose levels. The patient was diagnosed with type 2 diabetes, he did not have diabetes before commencing the treatment. As a corrective treatment the patient recieved metformin and then fainted.	Metformin hydrochloride, olanzapine ceased, switched to quetiapine fumarate.

Medicine Details:

ZYPREXA (Suspected)	Reason: Unspecifid affective psychosis
Tablet	2.5 Milligram
	Daily
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
23/03/2007	Serum glucose				His fasting glucose levels rose up to 7.0mmol/L. Prior to starting olanzapine, and when the patient is off the olanzapine , the patient's fasting blood glucose levies were below 6.0 mmol/L.

Additional Information:

Historical AR Malaise
Patient tried lithium and was crook and felt very sick.
Historical AR Hepatitis
Patient tired sodium valproate and developed a hepatitis-like-thing, with elevated liver function tests.
Reporting psyhchiatrist stated that the patient needs to loose weight and has a family history of diabetes.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 227271

Seq: 1

Gender: M

Reported: 03/04/2007

Weight: 0.00

Hospitalisation:

Age: 65Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		Thrombocytopenia. Low platelets	Treatment Discontinued

Medicine Details:

ZYPREXA (Suspected)	Reason:
Batch:	Started: 15/09/2006 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
03/04/2007	Platelets				Platelet count 70,000 Low.

Additional Information:

Patient experienced symptoms after being on olanzapine for 6 months.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 227973

Seq: 1

Gender: M

Reported: 26/04/2007

Weight: 102.00

Hospitalisation:

Age: 17

Onset Date: 15/10/2006

DOB: 02/11/1988

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac failure congestive	Life threatening	Patient experienced cardiomyopathy.	Ceased drug.

Medicine Details:

EPILIM (Other drug)		Reason:	
	1.5 Gram	Daily	
Batch:	Started:	L TERM	Stopped:
ZYPREXA (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 15/07/2006	Stopped:	21/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
26/04/2007	Ejection fraction				

Additional Information:

intellectual disability, midline abnormalities, high palate, hypotonia, exomphalos, normal karyotype.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 228265 **Seq:** 1 **Gender:** M
Reported: 07/05/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 48Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abnormal sleep-related event	Caused or prolonged inpatient hospitalisation	Patient had apparent hallucinations, during the day would "drive like an idiot" had swerved across 3 lanes of traffic. After a friend hung himself there were several occasions when he would wander near his place "talking to the trees" at night. He had no memory of these events.	
Amnesia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

MS CONTIN (Other drug)		Reason:	
	60.0 Milligram	Daily	
Batch:	Started:	L TERM	Stopped:
OXAZEPAM (Other drug)		Reason:	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started:	L TERM	Stopped: Continued.
ENDONE (Other drug)		Reason:	
	3.0 Dose Unspecified	Daily	
Batch:	Started:	L TERM	Stopped: Continued.
ZYPREXA (Suspected)		Reason:	
	5.0 Milligram	Daily	
Batch:	Started: 31/05/2005	L TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

No suicidal ideation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 228265 **Seq:** 1 **Gender:** M
Reported: 07/05/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 48Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination	Caused or prolonged inpatient hospitalisation		
Stereotypy	Caused or prolonged inpatient hospitalisation		
Suicidal behaviour	Caused or prolonged inpatient hospitalisation		

Medicine Details:

STILNOX (Suspected)		Reason: Specific disorders of sleep	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped: 15/02/2005
EFEXOR-XR (Suspected)		Reason:	
Capsule	150.0 Milligram	Daily	Oral
Batch:	Started: 05/07/2005	L TERM	Stopped:

Laboratory Investigations:

Additional Information:

No suicidal ideation.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydys

Report Details:

Case Number: 228346 **Seq:** 1 **Gender:** F
Reported: 09/05/2007 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 46
Onset Date: 24/03/2007 **DOB:** 17/01/1961
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhabdomyolysis	Life threatening	Patient developed rhabdomyolysis, fevers, rigor, suspected URTI and a fall before admission.	
Chills	Life threatening		
Neuroleptic malignant syndrome	Life threatening		
Pyrexia	Life threatening		

Medicine Details:

FLUVOXAMINE MALEATE (Other drug)		Reason:	
Tablet	100.0 Milligram	Oral	
Batch:	Started:	Stopped:	
QUETIAPINE (Other drug)		Reason:	
Tablet	400.0 Milligram	Oral	
Batch:	Started:	Stopped:	
CARBAMAZEPINE (Other drug)		Reason:	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	0
Aripiprazole (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	24/03/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Psychosis, depression, asthma and epilepsy.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Date Range: 1 Jan 2003 To 31 Dec 2007 Unclear causality excluded GM medicines Only Tradenames:
OLANZAPINE,ZYPREXA,Zyprexa IM,Zyprexa Zydis

Report Details:

Case Number: 228346 **Seq:** 1

Reported: 09/05/2007

Hospitalisation: Admitted to hospital

Onset Date: 24/03/2007

Outcome: Not yet recovered

Gender: F

Weight: 0.00

Age: 46

DOB: 17/01/1961

Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected)

Reason:

7.5 Milligram

Daily

Batch:

Started:

Stopped: 24/03/2007

Laboratory Investigations:

Additional Information:

History: Psychosis, depression, asthma and epilepsy.