



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 187560

Seq: 1

Gender: M

Reported: 25/06/2003

Weight: 0.00

Hospitalisation:

Age: 54

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sleep disorder		Patient has noticed difference in the quality of his sleep. Patient described it as a "prolonged blackout", feels like he is "half-asleep", "half-awake" and has not had any dreams.	

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram Daily Oral
Batch:	Started: L TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Cipramil and Eilim.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 187879

Seq: 1

Gender: M

Reported: 27/06/2003

Weight: 90.00

Hospitalisation:

Onset Date: 23/06/2003

Age: 36

DOB: 14/03/1967

Outcome: Recovered

24/06/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Condition aggravated	Required Visit to Doctor	Increased psychotic Symptoms, tremor and feeling cold.	
Tremor	Required Visit to Doctor	Increased psychotic Symptoms, tremor and feeling cold.	
Feeling cold	Required Visit to Doctor	Increased psychotic Symptoms, tremor and feeling cold.	

Medicine Details:

Aripiprazole (Suspected)	Reason: Schizophrenia		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 16/06/2003	Stopped:	23/06/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 191364
Reported: 16/10/2003

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 35
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dizziness		Tachycardia, Dizzines.	Felt faint while exercising with weights.
Tachycardia		Tachycardia, Dizzines. Felt faint while exercising with weights.	Felt faint while exercising with weights.

Medicine Details:

Abilify (Suspected)	Reason: Schizophrenia	
15.0 Milligram	Daily	Oral
Batch:	Started: 03/08/2003	Stopped: 15/09/2003
EDRONAX (Suspected)	Reason: Depression	
Tablet	8.0 Milligram	Daily
Batch:	Started: 21/07/2003	Stopped: 15/09/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
16/10/2003	Other data				

Additional Information:

Patient also taking Seroquel and Topamax.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192069 **Seq:** 1 **Gender:** M
Reported: 11/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 30
Onset Date: 07/10/2003 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis	Caused or prolonged inpatient hospitalisation	Deep vein thrombosis.	He was treated with subcutaneous low molecular weight heparin and recovered. He is currently on Warfarin.

Medicine Details:

Abilify (Suspected)	Reason: Schizophrenia
Tablet	30.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Abilify started Oct 2003.
The patient is obese and a smoker. He has no other risk factors for DVT. There is no family history of hypercoaguable disorder.
Other drugs used: Clozapine, Diazepam and Venlafaxine.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192275
Reported: 17/11/2003

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 30/10/2003
Outcome: Recovered

Age: 56
DOB: 03/08/1947
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypersensitivity Lip swelling Pruritus Rash papular		Hypersensitivity	

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason:		
	1.0 Dose Unspecified Daily		
Batch:	Started:	Stopped:	
Abilify (Suspected)	Reason: Schizophrenia		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 27/10/2003	Stopped: 02/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192277	Seq: 1	Gender: F
Reported: 17/11/2003		Weight: 0.00
Hospitalisation:		Age: 37
Onset Date: 12/09/2003		DOB: 08/07/1966
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation	Vomiting, headache, agitation and anxiety.	
Agitation	Caused or prolonged inpatient hospitalisation		
Anxiety	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)		Reason: Hallucinations	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 12/09/2003	Stopped: 12/09/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Within 1-2 hours after receiving her initial dose of Aripiprazole, 15 mg/day.
 Patient also administered: Edronax, Zyprexa.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192277

Seq: 1

Gender: F

Reported: 17/11/2003

Weight: 0.00

Hospitalisation:

Age: 37

Onset Date: 12/09/2003

DOB: 08/07/1966

Outcome: Recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

Abilify (Suspected)	Reason: Hallucinations		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 12/09/2003	Stopped: 12/09/2003	

Laboratory Investigations:

Additional Information:

Within 1-2 hours after receiving her initial dose of Aripiprazole, 15 mg/day.
Patient also administered: Edronax, Zyprexa.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192358	Seq: 1	Gender: F
Reported: 20/11/2003		Weight: 0.00
Hospitalisation:		Age: 36
Onset Date: 07/11/2003		DOB: 04/03/1967
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation	Increased CK level, increased drug level, confused, delirious, light hyperreflexia, tachycardic.	
Confusional state	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOPINE (Interaction)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
Abilify (Interaction)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
VALIUM (Other drug)		Reason: Anxiety neurosis	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 07/11/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192358	Seq: 1	Gender: F
Reported: 20/11/2003		Weight: 0.00
Hospitalisation:		Age: 36
Onset Date: 07/11/2003		DOB: 04/03/1967
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Interaction)		Reason: Unspecified schizophrenia	
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
Abilify (Interaction)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
VALIUM (Other drug)		Reason: Anxiety neurosis	
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 07/11/2003	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192358

Seq: 1

Gender: F

Reported: 20/11/2003

Weight: 0.00

Hospitalisation:

Age: 36

Onset Date: 07/11/2003

DOB: 04/03/1967

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

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

Medicine Details:

CLOPINE (Interaction)	Reason: Unspecified schizophrenia		
Tablet	400.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
Abilify (Interaction)	Reason:		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/11/2003	
VALIUM (Other drug)	Reason: Anxiety neurosis		
Tablet	5.0 Milligram	As necessary	Oral
Batch:	Started:	Stopped: 07/11/2003	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192487 **Seq:** 1 **Gender:** M
Reported: 25/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 50
Onset Date: 25/09/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyponatraemia	Caused or prolonged inpatient hospitalisation	Hyponatraemia, paranoia, aggression, delusion, thinking abnormal, blood chloride, blood urea, blood creatinine all decreased.	
Aggression	Caused or prolonged inpatient hospitalisation		
Blood chloride decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Schizophrenia
Oral application	15.0 Milligram Daily Oral
Batch:	Started: 12/09/2003 Stopped: 05/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Chloride		08/10/2003	89 MMOL/L	
25/11/2003	Chloride		14/10/2003	88 MMOL/L	
25/11/2003	Creatinine		08/10/2003	58 MMOL/L	
25/11/2003	Creatinine		14/10/2003	70 MMOL/L	
25/11/2003	Potassium		08/10/2003	4.7 MMOL/L	
25/11/2003	Potassium		14/10/2003	4.6 MMOL/L	
25/11/2003	Sodium		08/10/2003	127 MMOL/L	

Additional Information:

Patient also administered: Zyprexa, Moducare, Largactil, Solian.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192487 **Seq:** 1 **Gender:** M
Reported: 25/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 50
Onset Date: 25/09/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine decreased	Caused or prolonged inpatient hospitalisation		
Blood urea decreased	Caused or prolonged inpatient hospitalisation		
Delusion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Schizophrenia
Oral application	15.0 Milligram Daily Oral
Batch:	Started: 12/09/2003 Stopped: 05/10/2003

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/11/2003	Sodium		14/10/2003	127 MMOL/L	
25/11/2003	Urea		08/10/2003	2.2 MMOL/L	
25/11/2003	Urea		14/10/2003	2.5 MMOL/L	

Additional Information:

Patient also administered: Zyprexa, Moducare, Largactil, Solian.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192487 **Seq:** 1 **Gender:** M
Reported: 25/11/2003 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 50
Onset Date: 25/09/2003 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paranoia	Caused or prolonged inpatient hospitalisation		
Thinking abnormal	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Schizophrenia
Oral application	15.0 Milligram Daily Oral
Batch:	Started: 12/09/2003 Stopped: 05/10/2003

Laboratory Investigations:

Additional Information:

Patient also administered: Zyprexa, Moducare, Largactil, Solian.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192881	Seq: 1	Gender: M
Reported: 05/12/2003		Weight: 80.00
Hospitalisation:		
Onset Date: 29/11/2003		Age: 31
Outcome: Recovered	30/11/2003	DOB: 21/02/1972
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amnesia	Required Visit to Doctor	Gross amnesia and psychomotor slowing, leading to pushbike accident.	
Psychomotor skills impaired	Required Visit to Doctor		
Road traffic accident	Required Visit to Doctor		

Medicine Details:

Abilify (Interaction)		Reason:	
Tablet	7.5 Milligram	Daily	Oral
Batch:	Started: 25/11/2003	Stopped: 30/11/2003	
STILNOX (Interaction)		Reason: Specific disorders of sleep	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Abilify slowing metabolism of Stilnox via cytochrome 450 344 and subsequent amnesia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 193274	Seq: 1	Gender: F
Reported: 17/12/2003		Weight: 0.00
Hospitalisation:		Age: 17
Onset Date: 05/12/2003		DOB: 15/01/1986
Outcome: Recovered	05/12/2003	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Depressed level of consciousness		Consciousness impaired.	Required ICU admission, given Flumazenil 500mg iv with rapid response.

Medicine Details:

SEROQUEL (Interaction)		Reason: Otr spec symp psychopathol nec	
Batch:	Started:	Stopped:	
MIDAZOLAM (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	10.0 Milligram	As necessary	Intramuscular
Batch:	Started:	Stopped:	
DROPERIDOL (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	5.0 Milligram	As necessary	Intramuscular
Batch:	Started:	Stopped:	
Abilify (Interaction)		Reason: Otr spec symp psychopathol nec	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 26/11/2003	Stopped: 05/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking Levlen, Ferro-Gradmet, Nicabate, Mylanta.
 Aripiprazole commenced 1 week prior (26/11/03).
 Multiple drug interactions many have pre this event.cipitated



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 193274

Seq: 1

Gender: F

Reported: 17/12/2003

Weight: 0.00

Hospitalisation:

Onset Date: 05/12/2003

Age: 17

DOB: 15/01/1986

Outcome: Recovered

05/12/2003

Causality: Causality possible

Reaction Details:

Medicine Details:

LAMICTAL (Interaction)		Reason:	
Tablet	137.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
DIAZEPAM (Interaction)		Reason: Otr spec symp psychopathol nec	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
EPILIM (Interaction)		Reason:	
Tablet	1000.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

Patient was also taking Levlen, Ferro-Gradmet, Nicabate, Mylanta.
Aripiprazole commenced 1 week prior (26/11/03).
Multiple drug interactions many have pre this event.cipitated



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 193937 **Seq:** 1 **Gender:** F
Reported: 16/01/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 19
Onset Date: 10/12/2003 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Extrapyramidal disorder, akathisa, jaw stiffness, tongue protrusion and stiff hands.	Ceased Abtlify, given benztropine 1mg/day.

Medicine Details:

Abilify (Suspected)	Reason:
Batch:	Started: Stopped:
LARGACTIL (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was also taking tegretol and Largactil.
Medical history was significant for pervasive developmental disorder, petit mal epilepsy, and allergy to ethosuxomide and sodium valproate. The patient was undergoing a course of electroconvulsive therapy at the time of this report.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 193960

Seq: 1

Gender: M

Reported: 19/01/2004

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 19/12/2003

DOB: 05/04/1962

Outcome: Recovered

21/12/2003

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arthralgia	Caused or prolonged inpatient hospitalisation	Joint pain.	Ceased Aripiprazole.

Medicine Details:

Aripiprazole (Suspected)	Reason: Unspecified psychosis		
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 15/12/2003	Stopped: 19/12/2003	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 193966

Seq: 1

Gender: M

Reported: 19/01/2004

Weight: 121.00

Hospitalisation:

Age: 27

Onset Date: 17/12/2003

DOB: 26/09/1976

Outcome: Recovered

13/01/2004

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Required Visit to Doctor	Vomiting and diarrhoea.	Ceased Abilify
Diarrhoea	Required Visit to Doctor		

Medicine Details:

FLUPENTHIXOL DECANOATE (Other drug)	Reason:	
Injection	Intramuscular	
Batch:	Started:	Stopped:
Abilify (Suspected)	Reason:	
Tablet	Oral	
Batch:	Started: 16/12/2003	Stopped: 11/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 194604
Reported: 16/02/2004
Hospitalisation:
Onset Date: 09/02/2004
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 34
DOB: 21/08/1969
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Required Visit to Doctor	Dystonic reaction (stiff lower jaw, swollen tongue, difficulty talking, tightness in throat and stiff sore legs on walking).	Given 1mg IM Benztropine followed by 0.5mg/bd orally for 3 days.
Tongue oedema			

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason: Depression		
Tablet 30.0 Milligram Daily Oral			
Batch:	Started:	Stopped:	Contin
LORAZEPAM (Suspected)	Reason: Anxiety neurosis		
Tablet Dose Unspecified As necessary Oral			
Batch:	Started: 31/12/2003	Stopped:	Contin
Abilify (Suspected)	Reason: Schizophrenia		
Tablet 15.0 Milligram Daily Oral			
Batch:	Started: 31/12/2003	Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient has had a similar reaction to Risperidone 2mg/bd.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 195103	Seq: 1	Gender: M
Reported: 04/03/2004		Weight: 89.50
Hospitalisation:		Age: 28Y
Onset Date: 15/01/2004		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome, fever, tachycardia, CK increased, muscle rigidity (L>R in upper limbs), reflexes increased, sweating, mood swings.	Daily monitoring clinically, second - daily FBE/CK/LFT, cessation of medication.
Blood creatine phosphokinase incr			
Hyperhidrosis			
Hyperreflexia			
Mood swings			
Muscle rigidity			
Pyrexia			
Tachycardia			

Medicine Details:

Aripiprazole (Suspected)		Reason: Unspecified psychosis	
Tablet	45.0 Milligram	Daily	Oral
Batch:	Started: 06/01/2004	Stopped: 22/01/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
04/03/2004	Creatine		01/01/2004	61	
04/03/2004	Creatine		22/01/2004	356	
04/03/2004	Creatine		26/01/2004	238	

Additional Information:

Patient also administered: Sodium valproate, Clonazepam.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 196051	Seq: 1	Gender: M
Reported: 29/03/2004		Weight: 0.00
Hospitalisation:		Age: 41
Onset Date: 01/09/2003		DOB: 14/08/1962
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Query neuroleptic malignant, febrile, muscle aches, rigors and night sweats.	Treatment with diazepam, discontinuation of reboxetine and amisulpride and unspecified dose reduction of paroxetine and periciazine.
Agitation	Caused or prolonged inpatient hospitalisation		
Chills			

Medicine Details:

Abilify (Suspected)	Reason:
Batch:	Started: Stopped:
NEULACTIL (Suspected)	Reason:
Batch:	Started: Stopped:
AROPAX (Suspected)	Reason:
Batch:	Started: 03/07/2003 Stopped:
EDRONAX (Suspected)	Reason: Depression
Tablet	8.0 Milligram Daily Oral
Batch:	Started: 26/08/2003 Stopped: 22/01/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Aripiprazole later resumed as schizophrenic symptoms recurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 196051	Seq: 1	Gender: M
Reported: 29/03/2004		Weight: 0.00
Hospitalisation:		Age: 41
Onset Date: 01/09/2003		DOB: 14/08/1962
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia	Caused or prolonged inpatient hospitalisation		
Myalgia			
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		
Night sweats			

Medicine Details:

Abilify (Suspected)	Reason:
Batch:	Started: Stopped:
NEULACTIL (Suspected)	Reason:
Batch:	Started: Stopped:
AROPAX (Suspected)	Reason:
Batch:	Started: 03/07/2003 Stopped:
EDRONAX (Suspected)	Reason: Depression
Tablet	8.0 Milligram Daily Oral
Batch:	Started: 26/08/2003 Stopped: 22/01/2004

Laboratory Investigations:

Additional Information:

Aripiprazole later resumed as schizophrenic symptoms recurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 196051	Seq: 1	Gender: M
Reported: 29/03/2004		Weight: 0.00
Hospitalisation:		Age: 41
Onset Date: 01/09/2003		DOB: 14/08/1962
Outcome: Recovered		Causality: Causality possible

Reaction Details:

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

Medicine Details:

Abilify (Suspected)	Reason:
Batch:	Started: Stopped:
NEULACTIL (Suspected)	Reason:
Batch:	Started: Stopped:
AROPAX (Suspected)	Reason:
Batch:	Started: 03/07/2003 Stopped:
EDRONAX (Suspected)	Reason: Depression
Tablet	8.0 Milligram Daily Oral
Batch:	Started: 26/08/2003 Stopped: 22/01/2004

Laboratory Investigations:

Additional Information:

Aripiprazole later resumed as schizophrenic symptoms recurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 196398	Seq: 1	Gender: F
Reported: 13/04/2004		Weight: 50.00
Hospitalisation:		Age: 15
Onset Date: 24/03/2004		DOB: 06/01/1989
Outcome: Recovered	26/03/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension		Hypotensive (66/26).	Aripiprazole withheld then ceased. IV fluids given but was hard to re-establish BP.
Drug interaction			

Medicine Details:

DROPERIDOL (Interaction)		Reason: Otr spec symp psychopathol nec	
Injection	10.0 Milligram	As necessary	Intramuscular
Batch:	Started:	Stopped:	
Abilify (Interaction)		Reason: Anxiety neurosis	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 04/03/2004	Stopped: 24/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Buspirone, Lamictal, Centrum and Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 196570
Reported: 19/04/2004

Seq: 1

Gender: M
Weight: 70.00
Age: 52
DOB: 02/01/1952
Causality: Causality probable

Hospitalisation:

Onset Date: 22/03/2004
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperhidrosis	Required Visit to Doctor	Patient experienced profuse sweating, immediate severe nausea and vomiting with hiccups.	
Hiccups	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

Aripiprazole (Suspected)	Reason: Schizophrenia		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 22/03/2004	Stopped: 28/03/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 196781 **Seq:** 1 **Gender:** F
Reported: 23/04/2004 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 56
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting	Caused or prolonged inpatient hospitalisation	Severe persistent vomiting resolving after 4 days	

Medicine Details:

Abilify (Suspected)	Reason: Schizophrenia
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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 197073	Seq: 1	Gender: M
Reported: 06/05/2004		Weight: 0.00
Hospitalisation:		Age: 44
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuropathy peripheral		Peripheral neuropathy.	

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 197298

Seq: 1

Gender: F

Reported: 12/05/2004

Weight: 0.00

Hospitalisation:

Age: 24Y

Onset Date: 27/12/2003

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Mania Agitation Obsessive thoughts Suicidal ideation		Mania, agitation, obsessive thoughts, suicidal ideation.	Ceased Abilift

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 25/12/2003 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

One month later, the patient committed suicide.
Past medical history bipolar disorder from the age of 16 and two suicide attempts.
Patient was also taking Quetiapine, Luvox, Topiramate.
Followup information: physician did not believe aripiprazole was the cause of the suicide based on the short course of aripiprazole and the discontinuation one month prior to the suicide.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 197651 **Seq:** 1 **Gender:** F
Reported: 27/05/2004 **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
Mania	Caused or prolonged inpatient hospitalisation	Manic episode.	
Drug ineffective	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Schizo-affective type psychos
Tablet	Dose Unspecified Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 197656 **Seq:** 1 **Gender:** F
Reported: 27/05/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 34Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	Psychotic disorder	Hospitalised

Medicine Details:

Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	Dose Unspecified Oral
Batch:	Started: S TERM Stopped: 01/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 198164

Seq: 1

Gender: M

Reported: 15/06/2004

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sedation		Sedation.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient also taking Lithium and Sodium Valproate.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 198574	Seq: 1	Gender: M
Reported: 28/06/2004		Weight: 103.00
Hospitalisation:		Age: 23
Onset Date: 01/06/2004		DOB: 01/02/1981
Outcome: Recovered	21/06/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia	Required Visit to Doctor	Profound insomnia, nausea and vomiting. Relapse of schizophrenia.	Abilify ceased. Zyprexa restarted.
Schizophrenia	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

Abilify (Suspected)	Reason: Schizophrenia
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 05/04/2004 Stopped: 15/06/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 198644	Seq: 1	Gender: M
Reported: 02/07/2004		Weight: 55.00
Hospitalisation:		Age: 28
Onset Date: 15/06/2004		DOB: 27/12/1975
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Drowsy, dribbling, shuffling, unsteady, pseudoparkinsonism.	Stopped Abilify
Drooling			
Gait disturbance			
Parkinsonism			

Medicine Details:

Abilify (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 07/06/2004	Stopped: 18/06/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Symptoms worse despite reduction of dose.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 198989	Seq: 1	Gender: F
Reported: 16/07/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 99U
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Three seizures.	Abilify ceased.

Medicine Details:

Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	15.0 Milligram 1 time Oral
Batch:	Started: 29/05/2004 Stopped: 29/05/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

It was reported that this was the patient's first episode of psychosis and she had not had any previous antipsychotic treatment. Had total of 3 seizures.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 199249

Seq: 1

Gender: F

Reported: 20/07/2004

Weight: 0.00

Hospitalisation:

Age: 40

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Nocturnal seizures.	

Medicine Details:

Abilify (Suspected)	Reason:
Batch:	Oral
Started:	S TERM
Stopped:	Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 199361	Seq: 1	Gender: M
Reported: 23/07/2004		Weight: 0.00
Hospitalisation:		Age: 28
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Arrhythmia, dizziness, fatigue and malaise.	
Dizziness			
Fatigue			
Malaise			

Medicine Details:

Abilify (Suspected)	Reason: Schizophrenia
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: S TERM Stopped: Continuing

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was on four different medications for 'blood pressure/heart'. He has a history of cardiomyopathy which developed in 1999 while being treated with Clozapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 199568	Seq: 1	Gender: F
Reported: 02/08/2004		Weight: 70.00
Hospitalisation:		Age: 39
Onset Date: 30/06/2004		DOB: 02/01/1965
Outcome: Recovered	25/07/2004	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness	Required Visit to Doctor	Restlessness, muscle stiffness and acute euphonia, nausea.	
Akathisia	Required Visit to Doctor		
Blood creatine phosphokinase incr	Required Visit to Doctor		
Drug withdrawal syndrome	Required Visit to Doctor		
Euphoric mood	Required Visit to Doctor		
Musculoskeletal stiffness	Required Visit to Doctor		

Medicine Details:

LOVAN (Other drug)		Reason: Depression
Capsule	100.0 Milligram	Daily
Batch:	Started:	L TERM Stopped: 19/07/2004 0
STILNOX (Other drug)		Reason: Specific disorders of sleep
Tablet	10.0 Milligram	Daily
Batch:	Started:	Stopped: 0
Abilify (Suspected)		Reason:
Tablet	10.0 Milligram	Daily
Batch:	Started: 28/06/2004	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
02/08/2004	Creatine	(N=25-150)	13/07/2004	217	
02/08/2004	Creatine	(N=25-150)	27/07/2004	136	

Additional Information:

Abilify was reduced from 10mg/daily to 5mg/daily on 08/07/04 - 12/07/04.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 199568
Reported: 02/08/2004

Seq: 1

Gender: F
Weight: 70.00

Hospitalisation:

Onset Date: 30/06/2004
Outcome: Recovered

25/07/2004

Age: 39
DOB: 02/01/1965
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia	Required Visit to Doctor		
Nausea	Required Visit to Doctor		

Medicine Details:

LOVAN (Other drug)	Reason: Depression
Capsule	100.0 Milligram Daily
Batch:	Started: L TERM Stopped: 19/07/2004 0
STILNOX (Other drug)	Reason: Specific disorders of sleep
Tablet	10.0 Milligram Daily
Batch:	Started: Stopped: 0
Abilify (Suspected)	Reason:
Tablet	10.0 Milligram Daily
Batch:	Started: 28/06/2004 Stopped: 0

Laboratory Investigations:

Additional Information:

Abilify was reduced from 10mg/daily to 5mg/daily on 08/07/04 - 12/07/04.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 199795	Seq: 1	Gender: F
Reported: 09/08/2004		Weight: 0.00
Hospitalisation: Treated in Accident/Emergency Department		Age: 34Y
Onset Date: 01/07/2004		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension	Treated in outpatient department only	Dizziness and fainting, syncopal episodes, loss of consciousness with hypertension and bradycardia.	
Bradycardia	Treated in outpatient department only		
Dizziness	Treated in outpatient department only		

Medicine Details:

TEGRETOL (Other drug)	Reason:
	Dose Unspecified
Batch:	Started: Stopped:
LAMICTAL (Other drug)	Reason:
	Dose Unspecified
Batch:	Started: Stopped:
THYROXINE SODIUM (Other drug)	Reason:
	Dose Unspecified
Batch:	Started: Stopped:
QUILONUM SR (Other drug)	Reason:
	1.0 Gram Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/08/2004	Other data				Normal QT interval.

Additional Information:

History: Nodular goiter (hypothyroidism)



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 199795 **Seq:** 1 **Gender:** F
Reported: 09/08/2004 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 34Y
Onset Date: 01/07/2004 **DOB:**
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Syncope	Treated in outpatient department only		

Medicine Details:

Abilify (Suspected)	Reason: Unspecifid affective psychosis
Tablet	10.0 Milligram Daily
Batch:	Started: 01/07/2004 Stopped: 02/07/2004

Laboratory Investigations:

Additional Information:

History: Nodular goiter (hypothyroidism)



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 199812	Seq: 1	Gender: F
Reported: 10/08/2004		Weight: 0.00
Hospitalisation:		Age: 47
Onset Date: 24/06/2004		DOB: 18/08/1956
Outcome: Recovered without treatment		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures, found by friend who witnessed seizure, further episode witnessed by ED RMO at 1700-patient became unresponsive, increased tone & stiffness throughout, lasted <10 secs(no incontinence or tongue biting), felt unwell, nauseated, lapsed in and out of consciousness.	No treatment.
Malaise			
Nausea			
Somnolence			

Medicine Details:

Abilify (Suspected)	Reason: Unspecifid affective psychosis
Tablet	15.0 Milligram 1 time Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200145	Seq: 1	Gender: M
Reported: 19/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 19Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Adrenergic syndrome	Caused or prolonged inpatient hospitalisation	Marked adrenergic response, anxiety, nervousness, insomnia, rapid pulse, dilated pupils, agitation, raised creatine phosphokinase levels, elevated blood pressure, pectoral, stomach and thigh myalgia and an abnormal echocardiogram.	Observation and investigation in ICU, cessation of antipsychotics and Reboxetine.
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Interaction)	Reason: Schizophrenia
15.0 Milligram	Daily
Batch:	Started: 22/07/2004 Stopped: 05/08/2004 0
EDRONAX (Interaction)	Reason: Depression
8.0 Milligram	Daily
Batch:	Started: 14/05/2004 Stopped: 30/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
19/08/2004	Creatine				CPK - 800; CPK - 400; 11/08/2004 CPK - 200
19/08/2004	Echocardiogram				Abnormal Echocardiogram which showed reduction in ejection fraction from 76% to 63% with some inferior/septal hypokinesia.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200145 **Seq:** 1 **Gender:** M
Reported: 19/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 19Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Drug interaction	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Interaction)	Reason: Schizophrenia
15.0 Milligram Daily	
Batch:	Started: 22/07/2004 Stopped: 05/08/2004 0
EDRONAX (Interaction)	Reason: Depression
8.0 Milligram Daily	
Batch:	Started: 14/05/2004 Stopped: 30/07/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200145	Seq: 1	Gender: M
Reported: 19/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 19Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Echocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		
Insomnia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Interaction)	Reason: Schizophrenia
15.0 Milligram	Daily
Batch:	Started: 22/07/2004 Stopped: 05/08/2004 0
EDRONAX (Interaction)	Reason: Depression
8.0 Milligram	Daily
Batch:	Started: 14/05/2004 Stopped: 30/07/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200145	Seq: 1	Gender: M
Reported: 19/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 19Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Myalgia	Caused or prolonged inpatient hospitalisation		
Mydriasis	Caused or prolonged inpatient hospitalisation		
Nervousness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Interaction)	Reason: Schizophrenia
15.0 Milligram	Daily
Batch:	Started: 22/07/2004 Stopped: 05/08/2004 0
EDRONAX (Interaction)	Reason: Depression
8.0 Milligram	Daily
Batch:	Started: 14/05/2004 Stopped: 30/07/2004

Laboratory Investigations:

Additional Information:



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200145 **Seq:** 1 **Gender:** M
Reported: 19/08/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 19Y
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

Abilify (Interaction)	Reason: Schizophrenia
15.0 Milligram Daily	
Batch:	Started: 22/07/2004 Stopped: 05/08/2004 0
EDRONAX (Interaction)	Reason: Depression
8.0 Milligram Daily	
Batch:	Started: 14/05/2004 Stopped: 30/07/2004

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200357	Seq: 1	Gender: M
Reported: 27/08/2004		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Constipation		Patient also experienced constipation over the last few weeks. Patient had tried Zyban last year and felt constipated	
Hallucination, auditory		Patient started taking Zyban 6-7wks ago. Patient also taking Abilify, started taking 2wks ago. Experienced auditory hallucinations 2wks ago, "when I'm going to sleep or upon waking it sounds like a rock on the roof". Patient noticed this symptom more "when a bit stressed". Patient had tried Zyban last year but did not notice auditory hallucinations.	

Medicine Details:

ZYBAN SR (Suspected)		Reason:	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	0
Abilify (Suspected)		Reason:	
Tablet		Dose Unspecified	Oral
Batch:	Started:	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200429	Seq: 1	Gender: F
Reported: 30/08/2004		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 21
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	Experienced hypotension which caused her to fall.	
Fall	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SOLIAN (Suspected)	Reason:
Batch:	Started:
	Stopped:
Abilify (Suspected)	Reason:
Tablet	15.0 Milligram Daily Oral
Batch:	Started:
	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200465	Seq: 1	Gender: M
Reported: 01/09/2004		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tardive dyskinesia		Patient experienced tardive dyskinesia.	Dose reduced to 15mg.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient experienced tardive dyskinesia (TD) while taking other atypical atypical antipsychotics. When put on Aripiprazole 15mg, the symptoms subsided. When the dose was increased to 20mg, the TD returned. The dose has since been decreased to 15mg.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 200639

Seq: 1

Gender: M

Reported: 08/09/2004

Weight: 0.00

Hospitalisation:

Age: 72

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Drooling Speech disorder Tongue oedema		Dystonia, tongue oedema and speech disorder, drooling.	Ceased Abilify.

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped: 13/04/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient has now ceased treatment with Aripiprazole and has experienced a possible relapse. History of: diabetes mellitus, myocardial ischaemia, hypertension, smoker, blood cholesterol increased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 201046

Seq: 1

Gender: F

Reported: 22/09/2004

Weight: 80.00

Hospitalisation:

Age: 37

Onset Date: 25/08/2004

DOB: 09/04/1967

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Amenorrhoea		Ammenonhea (2 periods missed) and lactation.	
Galactorrhoea			

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 18/08/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 201058 **Seq:** 1 **Gender:** F
Reported: 22/09/2004 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20
Onset Date: 15/08/2004 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder	Caused or prolonged inpatient hospitalisation	Worsening of psychosis within a couple of days of ceasing Aripiprazole. She was also mildly depressive with schizoffective disease.	Benzodiazepines as needed and Aripiprazole recommenced in the hospital.
Depression	Caused or prolonged inpatient hospitalisation		
Drug withdrawal syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 201458	Seq: 1	Gender: F
Reported: 05/10/2004		Weight: 75.00
Hospitalisation:		Age: 40
Onset Date: 15/09/2004		DOB: 31/12/1963
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Salivary hypersecretion	Required Visit to Doctor	Increased salivation, tetany and hypertonia.	Abilify ceased.
Hypertonia	Required Visit to Doctor		
Tetany	Required Visit to Doctor		

Medicine Details:

Lexapro (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 0
NEXIUM (Other drug)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 0
INDERAL (Other drug)		Reason:	
Tablet	80.0 Milligram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
Abilify (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 15/08/2004	Stopped:	01/10/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 201580	Seq: 1	Gender: M
Reported: 08/10/2004		Weight: 75.00
Hospitalisation:		Age: 42
Onset Date: 27/09/2004		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Upper respiratory tract infection	Treated in outpatient department only	note described as "upper respiratory tract symptoms" coinciding with prescription of Aripiprazole.	Referred to GP
Drug ineffective	Treated in outpatient department only		

Medicine Details:

Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	15.0 Milligram 1 time Oral
Batch:	Started: 27/09/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 201751	Seq: 1	Gender: M
Reported: 15/10/2004		Weight: 0.00
Hospitalisation:		Age: 23Y
Onset Date: 23/09/2004		DOB:
Outcome: Recovered	26/09/2004	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness		Patient developed restlessness unable to sit still, and hiccups.	Ceased Abilify
Hiccups			

Medicine Details:

AVANZA (Other drug)	Reason:
30.0 Milligram	
Batch:	Started: Stopped:
PAXAM (Other drug)	Reason:
4.0 Dose Unspecified	
Batch:	Started: Stopped:
SOLIAN (Other drug)	Reason:
400.0 Milligram	
Batch:	Started: Stopped: 20/09/2004
Abilify (Other drug)	Reason:
Tablet	15.0 Milligram Oral
Batch:	Started: 22/09/2004 Stopped: 22/09/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 201751
Reported: 15/10/2004

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 23/09/2004
Outcome: Recovered

26/09/2004

Age: 23Y
DOB:
Causality: Causality probable

Reaction Details:

Medicine Details:

Abilify (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 21/09/2004	Stopped:	21/09/2004
Abilify (Suspected)		Reason:	
Tablet	20.0 Milligram	Daily	Oral
Batch:	Started: 23/09/2004	Stopped:	23/09/2004 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202406	Seq: 1	Gender: M
Reported: 09/11/2004		Weight: 105.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date: 06/10/2004		DOB: 21/07/1975
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced neuroleptic malignant syndrome, loss of consciousness, hyperhidrosis, body temperature increased, psychotic rebound and sweating.	Treated with Cabergoline. Patient had discontinued all the neuroleptic medications and was taking one of the new anti-parkinsonian drug.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Blood pressure increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:
Batch:	Started:
	Stopped:
Abilify (Suspected)	Reason:
Tablet	45.0 Milligram
	Oral
Batch:	Started: 06/10/2004
	Stopped: 06/10/2004 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
	Daily
	Oral
Batch:	Started: 06/09/2004
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
09/11/2004	Creatine		06/10/2004	3770	
09/11/2004	Creatine		07/10/2004	9840	
09/11/2004	Creatine		08/10/2004	8000	
09/11/2004	Creatine		09/10/2004	3160	
09/11/2004	Creatine		14/10/2004	1650	

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg. He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202406 **Seq:** 1 **Gender:** M
Reported: 09/11/2004 **Weight:** 105.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/10/2004 **DOB:** 21/07/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased	Caused or prolonged inpatient hospitalisation		
Delirium	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:	
Batch:	Started:	Stopped:
Abilify (Suspected)	Reason:	
Tablet	45.0 Milligram	Oral
Batch:	Started: 06/10/2004	Stopped: 06/10/2004 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 06/09/2004	Stopped:

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg. He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202406 **Seq:** 1 **Gender:** M
Reported: 09/11/2004 **Weight:** 105.00
Hospitalisation: Admitted to hospital **Age:** 29
Onset Date: 06/10/2004 **DOB:** 21/07/1975
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal	Caused or prolonged inpatient hospitalisation		
Loss of consciousness	Caused or prolonged inpatient hospitalisation		
Rebound effect	Caused or prolonged inpatient hospitalisation		

Medicine Details:

VALIUM (Other drug)	Reason:	
Batch:	Started:	Stopped:
Abilify (Suspected)	Reason:	
Tablet	45.0 Milligram	Oral
Batch:	Started: 06/10/2004	Stopped: 06/10/2004 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia	
Tablet	200.0 Milligram	Daily Oral
Batch:	Started: 06/09/2004	Stopped:

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg. He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202406	Seq: 1	Gender: M
Reported: 09/11/2004		Weight: 105.00
Hospitalisation: Admitted to hospital		Age: 29
Onset Date: 06/10/2004		DOB: 21/07/1975
Outcome: Unknown		Causality: Causality possible

Reaction Details:

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

Medicine Details:

VALIUM (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
Abilify (Suspected)	Reason:
Tablet	45.0 Milligram
Batch:	Started: 06/10/2004
	Stopped: 06/10/2004 0
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	200.0 Milligram
Batch:	Started: 06/09/2004
	Stopped:

Laboratory Investigations:

Additional Information:

Clozaril was commenced on 2 October 2001 and the daily dose was being progressively decreased from 550mg on 27 January 2004, to 200mg. He was rechallenged on an unspecified date, and he was tolerating 75mg of Clozaril. The first reaction was a psychotic rebound on 4 October after dose reduction of clozapine followed by NMS on 6 October.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202421	Seq: 1	Gender: M
Reported: 09/11/2004		Weight: 68.00
Hospitalisation: Hospitalisation prolonged		Age: 68
Onset Date: 27/10/2004		DOB: 10/12/1935
Outcome: Recovered	28/10/2004	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Within 3 hours of first dose presented with dizziness and postural hypotension followed by collapse. Required emergency transfer to general hospital, recovered with overnight observation. medication ceased.	Supportive treatment. Overnight stay in general hospital.
Dizziness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Suspected)	Reason:
10.0 Milligram	1 time
Oral	
Batch:	Started: 27/10/2004
	Stopped: 28/10/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202421 **Seq:** 1 **Gender:** M
Reported: 09/11/2004 **Weight:** 68.00
Hospitalisation: Hospitalisation prolonged **Age:** 68
Onset Date: 27/10/2004 **DOB:** 10/12/1935
Outcome: Recovered 28/10/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Suspected)	Reason:
10.0 Milligram	1 time Oral
Batch:	Started: 27/10/2004 Stopped: 28/10/2004 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202498	Seq: 1	Gender: M
Reported: 12/11/2004		Weight: 15.00
Hospitalisation: Admitted to hospital		Age: 2
Onset Date: 06/11/2004		DOB: 07/09/2002
Outcome: Recovered	07/11/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	The child was given an overdose of Aripiprazole 4mg/kg. Only effect was somnolence for 18 hours. Began cardiac monitoring. Child vomited once post charcoal.	

Medicine Details:

Aripiprazole (Suspected)	Reason:
Tablet	60.0 Milligram
	1 time
	Oral
Batch:	Started: 06/11/2004
	Stopped: 06/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202697	Seq: 1	Gender: M
Reported: 18/11/2004		Weight: 80.00
Hospitalisation:		Age: 25
Onset Date: 15/04/2004		DOB: 23/04/1978
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug withdrawal syndrome	Required Visit to Doctor	Patient experienced mild opiate withdrawal symptoms.	Abilify stopped.

Medicine Details:

Abilify (Interaction)	Reason: Unspecified schizophrenia
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 31/03/2004 Stopped: 15/04/2004
SUBUTEX (Interaction)	Reason:
Tablet	8.0 Milligram Daily Oral
Batch:	Started: 14/01/2004 Stopped:
ZYPREXA (Other drug)	Reason: Unspecified schizophrenia
	20.0 Milligram
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202886

Seq: 1

Gender: M

Reported: 19/11/2004

Weight: 94.00

Hospitalisation:

Age: 40

Onset Date: 13/11/2004

DOB: 01/02/1964

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspepsia	Required Visit to Doctor	Patient suffered heartburn, couldn't drink caffeine and had increased shakiness.	
Tremor	Required Visit to Doctor		

Medicine Details:

Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 01/11/2004 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify, Aripiprazole

Report Details:

Case Number: 203073	Seq: 1	Gender: M
Reported: 25/11/2004		Weight: 72.00
Hospitalisation: Admitted to hospital		Age: 28Y
Onset Date:		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation	The patient had raised creatine kinase and myositis.	
Myositis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203081 **Seq:** 1 **Gender:** M
Reported: 25/11/2004 **Weight:** 0.00
Hospitalisation: **Age:** 16Y
Onset Date: 29/10/2004 **DOB:**
Outcome: Recovered 03/11/2004 **Causality:** Causality certain

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Serotonin syndrome Blood creatine phosphokinase incr Clonus Hyperreflexia Hypertension Hypertonia Somnolence Tremor		Serotonin syndrome: drowsy, tremors, hyperreflexia, increased tone in the limbs, hypertension, increased creatine kinase and bilateral ankle clonus.	Abilify and Fluoxetine were withdrawn.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason: Anxiety neurosis
Capsule 30.0 Milligram Daily Oral	
Batch: Started: 17/08/2004 Stopped: 29/10/2004 0	
ZYPREXA (Other drug)	Reason: Otr spec symp psychopathol nec
8.0 Milligram Daily	
Batch: Started: 10/08/2004 Stopped: 26/10/2004 0	
Abilify (Suspected)	Reason: Otr spec symp psychopathol nec
Tablet 10.0 Milligram Daily Oral	
Batch: Started: 20/10/2004 Stopped: 29/10/2004 0	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Adverse reaction occurred not upon initiation of Ability, but when Zyprexa withdrawn. The physician did not consider fluoxetine or olanzapine to be suspect medications. Patient was rechallenged afte eight days with abilify and the same syndrome recurred.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203122	Seq: 1	Gender: F
Reported: 29/11/2004		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 14/10/2004		DOB: 07/05/1979
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Heart disease congenital Drug exposure during pregnancy Kidney malformation Limb malformation Trisomy 21		Heart disease congenital, kidney malformation, limb malformation.	Abortion, pregnancy terminated.

Medicine Details:

OLANZAPINE (Other drug)	Reason:
Batch:	Started: 01/05/2004 Stopped: 08/07/2004 0
HALOPERIDOL (Other drug)	Reason:
Batch:	Started: 01/08/2004 Stopped: 0
DICLOXACILLIN SODIUM (Other drug)	Reason:
Batch:	Started: 10/04/2004 Stopped: 03/06/2004 0
ALPRAZOLAM (Other drug)	Reason:
Batch:	Started: 01/05/2004 Stopped: 15/05/2004 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
29/11/2004	Other data				At 16 weeks an ultrasound revealed heart (absense of right ventricle) and renal tract abnormalities (left hydronephrosis) and the patient decided to terminate the pregnancy at 19 weeks. This was the patient's second pregancy with no developmental problems with the first child. Amniocentesis revealed no chromosome abnormalities. Follow-up: The foetal heart showed only three chambers with absence of the right ventricle. Only one outflow tract was seen. ...

Additional Information:

Gravidity 3, parity 1.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203122

Seq: 1

Gender: F

Reported: 29/11/2004

Weight: 0.00

Hospitalisation:

Onset Date: 14/10/2004

Age: 25

Outcome: Unknown

DOB: 07/05/1979

Causality: Causality possible

Reaction Details:

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 21/06/2004	Stopped: 24/08/2004	0
EFEXOR-XR (Suspected)	Reason:		
Capsule, modified release	75.0 Milligram	Daily	Oral
Batch:	Started: 07/01/2004	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
					... Foetal heart beat was 129 bpm. There was a marked hydronephrosis of the left kidney. Right renal outline was difficult to identify, but the kidney was probably short being at about the fifth percentile measuring 16 mm long. There was a prominent tubular structure in the abdomen which was probably a dilated left ureter. There was absence of the middle phalanx of the little finger of the foetal right hand.

Additional Information:

Gravidity 3, parity 1.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203204	Seq: 1	Gender: F
Reported: 01/12/2004		Weight: 85.00
Hospitalisation:		Age: 38Y
Onset Date: 15/09/2004		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Required Visit to Doctor	Became quite restless which developed into akathisia, pt would wake up each morning feeling nauseous then vomit.	Ceased Ability, was put on to Cogentin 2mg a day.
Restlessness	Required Visit to Doctor		
Vomiting	Required Visit to Doctor		

Medicine Details:

LITHICARB (Other drug)	Reason:
500.0 Milligram	
Batch:	Started: Stopped:
ZOLOFT (Other drug)	Reason:
8.0 Milligram	
Batch:	Started: Stopped:
Abilify (Suspected)	Reason:
Tablet 1.5 Dose Unspecified Daily	Oral
Batch:	Started: 08/09/2004 Stopped: 22/09/2004 2 weeks only

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Smoking 20/day; no alcohol and no illicit drugs.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203229	Seq: 1	Gender: M
Reported: 02/12/2004		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred		Patient developed difficulty focusing and increased, rapid blinking. He also experienced cramping and continuous movement of the tongue. Abilify was ceased.	Abilify dose reduced to 3.5mg/day. Had Botox in his eyelids.
Corneal reflex decreased			
Dyskinesia			
Muscle spasms			

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient could no longer work.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203308	Seq: 1	Gender: F
Reported: 06/12/2004		Weight: 54.00
Hospitalisation:		Age: 18Y
Onset Date: 08/10/2004		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Treated in outpatient department only		
Dystonia	Treated in outpatient department only	Dystonia of neck muscles	Treated at accident and emergency department with intramuscular cogentin which relieved the adverse reaction

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)		Reason:	
Capsule	20.0 Milligram	1 time	Oral
Batch:	Started: 20/08/2004	Stopped:	
Abilify (Suspected)		Reason: Unspecified psychosis	
Capsule	15.0 Milligram	1 time	Oral
Batch:	Started: 06/10/2004	Stopped: 08/10/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203530	Seq: 1	Gender: F
Reported: 14/12/2004		Weight: 55.00
Hospitalisation:		
Onset Date: 25/10/2004		Age: 86
Outcome: Recovered	05/11/2004	DOB: 28/12/1917
		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Bradykinesia	Required Visit to Doctor	Patient developed bradykinesia, mild rigidity and mild parkinsonism.	Ceased Aripiprazole.
Muscle rigidity	Required Visit to Doctor		
Parkinsonism	Required Visit to Doctor		

Medicine Details:

THYROXINE SODIUM (Other drug)		Reason: Myxedema	
Tablet	100.0 Microgram	Daily	Oral
Batch:	Started:	L TERM	Stopped:
DIGOXIN (Other drug)		Reason: Otr&nos disord of heart rhythm	
	62.0 Microgram	Daily	
Batch:	Started:	L TERM	Stopped:
OSTELIN 1000 (Other drug)		Reason: Other diseases of bone	
	1000.0	Daily	
Batch:	Started:	L TERM	Stopped:
CALTRATE (Other drug)		Reason: Other diseases of bone	
Tablet	600.0 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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203530

Seq: 1

Gender: F

Reported: 14/12/2004

Weight: 55.00

Hospitalisation:

Age: 86

Onset Date: 25/10/2004

DOB: 28/12/1917

Outcome: Recovered

05/11/2004

Causality: Causality probable

Reaction Details:

Medicine Details:

Aripiprazole (Suspected)	Reason: Unspecified psychosis		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 20/10/2004	Stopped: 25/10/2004	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203686

Seq: 1

Gender: U

Reported: 21/12/2004

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient experienced neuroleptic malignant syndrome which was considered medically serious.	Abilify ceased.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203689	Seq: 1	Gender: F
Reported: 21/12/2004		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
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	Patient experienced extrapyramidal symptoms.	

Medicine Details:

DIAZEPAM (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
BENZTROPINE MESYLATE (Other drug)	Reason:
Batch:	Started:
Batch:	Stopped:
LITHIUM CARBONATE (Other drug)	Reason:
Tablet	Oral
Batch:	Started:
Batch:	Stopped:
Abilify (Suspected)	Reason:
Tablet	30.0 Milligram Daily Oral
Batch:	Started: 08/11/2004
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203689

Seq: 1

Gender: F

Reported: 21/12/2004

Weight: 0.00

Hospitalisation: Admitted to hospital

Age: 99u

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected)

Reason:

8.0 Milligram

Daily

Oral

Batch:

Started:

Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203840

Seq: 1

Gender: M

Reported: 30/12/2004

Weight: 0.00

Hospitalisation:

Age: 41

Onset Date: 16/12/2004

DOB: 09/12/1963

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Treated in outpatient department only	Extrapyramidal side effects - tremor, increased muscle tone, cogwheel rigidity, abnormal gait, akathisia. Occurred around 16/12/04 after an increase in aripiprazole from 15mg to 30mg on the 4/11/04. NB: Aripiprazole was started on 30/07/04 at 7.5mg daily, later increased to 15mg on the 17/09/04.	Aripiprazole dose reduced to 15mg daily and olanzapine 5-10mg nocte added.
Akathisia	Treated in outpatient department only		

Medicine Details:

Aripiprazole (Suspected)	Reason:
Tablet	30.0 Milligram Daily Oral
Batch:	Started: 30/07/2004 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204007	Seq: 1	Gender: M
Reported: 07/01/2005		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 20/04/2004		DOB: 28/10/1978
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr		High creatinine kinase of 723U/L on 20/04/04. Afebrile and all other obs stable. CK 16723 and then 17500 on 22/04/04. CK then reduced to 15700 on 23/04/04 and 727 on 27/04/04. CK 184 on 10/05/04.	Aripiprazole ceased. Monitored for signs of renal impairment, oral fluids encouraged, urine alkalinised until pH 7.

Medicine Details:

QUETIAPINE (Other drug)		Reason:	
Tablet	600.0 Milligram	2 times	Oral
Batch:	Started:	Stopped:	
RANITIDINE (Other drug)		Reason:	
Tablet	150.0 Milligram	2 times	Oral
Batch:	Started:	Stopped:	
SODIUM VALPROATE (Other drug)		Reason:	
Tablet	1.0 Gram	2 times	Oral
Batch:	Started:	Stopped:	
Aripiprazole (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 07/04/2004	Stopped: 22/04/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204033 **Seq:** 1 **Gender:** F
Reported: 10/01/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 63Y
Onset Date: 12/11/2004 **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation	The patient experienced acute Parkinsonism or Extrapyramidal syndrome.	Aripiprazole ceased.

Medicine Details:

Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	60.0 Milligram Daily Oral
Batch:	Started: 25/09/2004 Stopped: 12/11/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204112	Seq: 1	Gender: M
Reported: 11/01/2005		Weight: 90.00
Hospitalisation:		
Onset Date: 08/12/2004		Age: 41
Outcome: Recovered	15/12/2004	DOB:
		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Palpitations	Required Visit to Doctor	The patient had palpitations, was sweaty and confused after being changed from Solian to Abilify, therefore some co-administration and could be a drug-drug interaction.	
Confusional state	Required Visit to Doctor		
Hyperhidrosis	Required Visit to Doctor		

Medicine Details:

Abilify (Interaction)		Reason: Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 15/11/2004	Stopped: 10/12/2004	
SOLIAN (Interaction)		Reason:	
	400.0 Milligram	Daily	Oral
Batch:	Started: 15/06/2004	S TERM	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204205	Seq: 1	Gender: F
Reported: 13/01/2005		Weight: 0.00
Hospitalisation:		Age: 22
Onset Date:		DOB: 16/01/1982
Outcome: Recovered	15/12/2004	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Extrapyramidal disorder		The patient experienced severe Parkinsonian with extrapyramidal side effects and akathisia.	Benztropine ceased.
Akathisia			

Medicine Details:

METFORMIN HYDROCHLORIDE (Other drug)		Reason: Diabetes mellitus	
Tablet	2.0 Milligram	Daily	Oral
Batch:	Started: 02/12/2004	Stopped:	
SODIUM VALPROATE (Other drug)		Reason:	
	1.0 Gram	Daily	Oral
Batch:	Started: L TERM	Stopped:	
Abilify (Suspected)		Reason: Unspecified psychosis	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 07/12/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204250	Seq: 1	Gender: M
Reported: 14/01/2005		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
Dystonia	Caused or prolonged inpatient hospitalisation	The patient experienced a neck rigidity.	
Nuchal rigidity	Caused or prolonged inpatient hospitalisation		

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Suspected)		Reason:	
Capsule		Oral	
Batch:	Started:	S TERM	Stopped:
Abilify (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	S TERM	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204340
Reported: 18/01/2005
Hospitalisation:
Onset Date: 20/09/2004
Outcome: Unknown

Seq: 1

Gender: M
Weight: 110.00
Age: 26
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Obsessive-compulsive disorder		When aripiprazole commenced on 20-sep-2004, the patient changed from a messy, disorganised man to one attempting to keep cupboards and drawers immaculately clean in both his and other people's houses (compulsive cleaning). The patient's behaviour then changed to excessive walking (resulting in sunburn, constantly blistering feet and dramatic weight loss).	Treated with 5mg Diazepam at night.

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 20/09/2004	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204583	Seq: 1	Gender: M
Reported: 25/01/2005		Weight: 100.00
Hospitalisation:		
Onset Date: 23/12/2004		Age: 28
Outcome: Recovered	07/01/2005	DOB: 04/02/1976
		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness	Required Visit to Doctor	The patient experienced increasing restlessness which was 'almost agonising' and caused irritability and insomnia.	Abilify ceased.
Insomnia	Required Visit to Doctor		
Irritability	Required Visit to Doctor		

Medicine Details:

RISPERDAL (Other drug)	Reason: Unspecified psychosis
1.0 Milligram	Daily
Batch:	Started:
Batch:	Stopped:
Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	10.0 Milligram
Daily	Oral
Batch:	Started: 20/12/2004
	Stopped: 04/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204828	Seq: 1	Gender: F
Reported: 02/02/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 40
Onset Date: 22/11/2004		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation	2 weeks ago noticed mouth lop sided, chewing on tongue subconsciously but consciously aware. Right facial drop and blurred vision.	Abilify ceased.
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Facial paresis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason: Depression
60.0 Milligram	
Batch:	Started: 15/12/2002 Stopped:
EPILIM (Other drug)	Reason: Unspecified schizophrenia
2.0 Gram	Oral
Batch:	Started: 15/12/2002 Stopped:
F.G.F. (Other drug)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: S TERM Stopped:
Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet 15.0 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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204828	Seq: 1	Gender: F
Reported: 02/02/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 40
Onset Date: 22/11/2004		DOB:
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason: Depression
60.0 Milligram	
Batch:	Started: 15/12/2002 Stopped:
EPILIM (Other drug)	Reason: Unspecified schizophrenia
2.0 Gram	Oral
Batch:	Started: 15/12/2002 Stopped:
F.G.F. (Other drug)	Reason:
1.0 Dose Unspecified Daily	
Batch:	Started: S TERM Stopped:
Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet 15.0 Milligram	Daily Oral
Batch:	Started: S TERM Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 205320

Seq: 1

Gender: U

Reported: 16/02/2005

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsion		Convulsion.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Physician was told by a patient that they experienced a seizure while on Abilify therapy. The physician did not believe the patient experienced a seizure.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 205410	Seq: 1	Gender: M
Reported: 21/02/2005		Weight: 74.00
Hospitalisation:		Age: 46
Onset Date: 15/01/2005		DOB: 17/07/1958
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypomania	Required Visit to Doctor	The patient developed hypomania. He had racing thoughts, was overactive and unable to sleep.	
Insomnia	Required Visit to Doctor		
Psychomotor hyperactivity	Required Visit to Doctor		
Thinking abnormal	Required Visit to Doctor		

Medicine Details:

OLANZAPINE (Other drug)	Reason: Unspecified schizophrenia
15.0 Milligram	Daily
Batch:	Started: 01/03/2004 Stopped: Continuing.
VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason: Depression
300.0 Milligram	Daily
Batch:	Started: L TERM Stopped:
ALPRAZOLAM (Other drug)	Reason: Anxiety neurosis
500.0 Microgram	Daily
Batch:	Started: L TERM Stopped:
Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet	15.0 Milligram
	Daily
Batch:	Started: 05/10/2004 Stopped: 15/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past history schizophrenia, PTSD and depression but never manic.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 205444
Reported: 22/02/2005
Hospitalisation:
Onset Date: 10/12/2004
Outcome: Recovered

Seq: 1

Gender: M
Weight: 142.00
Age: 28
DOB:
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache		The patient developed a severe continuous frontal headache soon after commencing Abilify. It resolved only when the drug was ceased.	Abilify ceased.

Medicine Details:

XANAX (Other drug)	Reason: Anxiety neurosis
3.0 Milligram Daily Oral	
Batch:	Started: L TERM Stopped: Continuing.
ZOLOFT (Other drug)	Reason: Depression
50.0 Milligram Daily Oral	
Batch:	Started: L TERM Stopped:
Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet 15.0 Milligram Daily Oral	
Batch:	Started: 09/12/2004 Stopped: 25/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Allergic to Penicillin.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 205816	Seq: 1	Gender: F
Reported: 07/03/2005		Weight: 0.00
Hospitalisation:		Age: 23Y
Onset Date:		DOB:
Outcome: Recovered	01/02/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Blood creatine phosphokinase incr Delirium Neuroleptic malignant syndrome Pyrexia Torticollis		The patient developed dystonia and increased CK, delirium/psychosis likely due to withdrawal of Aripiprazole in present of Risperidone depot.	Aripiprazole withdrawn. Treated with Anticholinergic, Clonazepam, oral hydration, supportive.

Medicine Details:

Aripiprazole (Interaction)	Reason: Unspecified schizophrenia
Tablet	Oral
Batch:	Started:
	Stopped: 0
RISPERIDONE (Interaction)	
	Reason: Unspecified schizophrenia
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Currently undergoing treatment for psychosis secondary to schizophrenia. Aripiprazole is drug interaction not suspected.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 205845

Seq: 1

Gender: M

Reported: 08/03/2005

Weight: 0.00

Hospitalisation:

Onset Date: 31/01/2005

Age: 43

DOB: 14/04/1961

Outcome: Recovered

24/02/2005

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased	Life threatening	Patient developed leucopenia and neutropenia.	Withdrew Abilify 30mg and Paroxetine. Monitored WBC.
Neutrophil count decreased	Life threatening		

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia		
Tablet	30.0 Milligram	Weekly	Oral
Batch:	Started: 07/09/2004	Stopped: 18/02/2005	0
GenRx Paroxetine (Suspected)	Reason: Depression		
Tablet	40.0 Milligram	Daily	Oral
Batch:	Started: 07/09/2004	Stopped: 10/02/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
08/03/2005	Neutrophils		31/01/2005	1.7	
08/03/2005	Neutrophils		15/02/2005	1.65	
08/03/2005	Neutrophils		24/02/2005	2.3	
08/03/2005	White blood cells		31/01/2005	3.3	
08/03/2005	White blood cells		15/02/2005	3.5	
08/03/2005	White blood cells		24/02/2005	4.6	

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 206124	Seq: 1	Gender: F
Reported: 17/03/2005		Weight: 60.00
Hospitalisation:		Age: 47
Onset Date:		DOB: 12/05/1957
Outcome: Recovered	09/03/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation		The patient experienced extreme agitation and a marked tremor.	Settled with ceasing Abilify and Benzodiazepam.
Tremor			

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	1.0 Gram	Oral	
Batch:	Started:	Stopped:	
Abilify (Suspected)		Reason: Unspecified psychosis	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/03/2005	Stopped: 07/03/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 206540	Seq: 1	Gender: F
Reported: 02/04/2005		Weight: 80.00
Hospitalisation: Required a visit to the doctor		Age: 52
Onset Date: 28/12/2004		DOB: 19/06/1952
Outcome: Recovered	20/01/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paranoia		The patient had been taking a batch of Abilify, which is subject to recall, for a couple of weeks. She became quite paranoid when she had previously been well for several months.	Abilify ceased, Risperidone commenced, then Haldol.
Drug ineffective			

Medicine Details:

SEROQUEL (Other drug)	Reason: Unspecified psychosis
Batch:	Started:
Stopped:	
NEXIUM (Other drug)	Reason:
Batch:	Started:
Stopped:	
LIPITOR (Other drug)	Reason:
Batch:	Started:
Stopped:	
Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	15.0 Milligram
	Daily
	Oral
Batch:	Started: 28/09/2004
	Stopped: 16/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 206608	Seq: 1	Gender: F
Reported: 04/04/2005		Weight: 65.00
Hospitalisation:		Age: 59
Onset Date: 20/01/2005		DOB: 24/12/1945
Outcome: Recovered	24/02/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance		The patient developed a shuffling, unsteady gait. Very anxious and unwilling to walk unless necessary. Rigidity of the limbs.	Abilify and Lexapro ceased.
Anxiety			
Muscle rigidity			

Medicine Details:

Abilify (Suspected)		Reason: Unspecified schizophrenia	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 31/08/2004	Stopped: 27/01/2005	
Lexapro (Suspected)		Reason: Depression	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 06/04/2004	Stopped: 27/01/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 206955	Seq: 1	Gender: F
Reported: 13/04/2005		Weight: 0.00
Hospitalisation:		Age: 51Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Consumer experienced a psychotic high, too heavy menstrual bleeding, and was harrassed by voices while on Aripiprazole therapy. Patient also experienced grogginess, tiredness, stiff muscles (biceps) and shortness of breath which could be a "touch of asthma or long standing sleep apnoea". Patient had a 3mm tumor on the pituitary. In addition, she reported that the prolactin levels were now normal. Patient also experienced nausea at the beginning but rarely at other times, which strongly resembled morning sickness.	

Medicine Details:

Abilify (Suspected)		Reason: Unspecified neurosis	
Tablet			Oral
Batch:	Started:		Stopped:
EPILIM (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient medical history was significant for elevated prolactin level. had heavy periods for many years. Medical condition: Asthma, sleep apnoea syndrome and blood prolactin increased.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 206955	Seq: 1	Gender: F
Reported: 13/04/2005		Weight: 0.00
Hospitalisation:		Age: 51Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyspnoea			
Fatigue			
Hallucination, auditory			
Hyperprolactinaemia			
Menorrhagia			
Musculoskeletal stiffness			
Nausea			
Somnolence			
Weight increased			

Medicine Details:

Abilify (Suspected)		Reason: Unspecified neurosis	
Tablet			Oral
Batch:	Started:		Stopped:
EPILIM (Suspected)		Reason:	
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:		Stopped:

Laboratory Investigations:

Additional Information:

Patient medical history was significant for elevated prolactin level. had heavy periods for many years. Medical condition: Asthma, sleep apnoea syndrome and blood prolactin increased.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 206963
Reported: 13/04/2005

Seq: 1

Gender: F
Weight: 93.00

Hospitalisation:

Onset Date: 20/03/2005
Outcome: Recovered

04/04/2005

Age: 28
DOB: 02/04/1976
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea		Severe nausea after starting Abilify.	Needed Maxolon 10mg.

Medicine Details:

AVAPRO (Other drug)	Reason:		
Tablet	500.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
LUVOX (Other drug)	Reason: Unspecified psychosis		
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	
Abilify (Suspected)	Reason: Prophylaxis		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 20/03/2005	Stopped: 31/03/2005	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207107 **Seq:** 1 **Gender:** F
Reported: 15/04/2005 **Weight:** 51.00
Hospitalisation: **Age:** 21
Onset Date: 30/03/2005 **DOB:** 14/04/1983
Outcome: Recovered 31/03/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Restlessness		Patient experienced restless limbs - feeling of 'blood flowing up and down arms' and restless, subjective feelings, drowsiness and akathisia.	Aripiprazole ceased. Treated with Bentropine.
Akathisia			
Somnolence			

Medicine Details:

Escitalopram (Other drug)	Reason: Depression
Tablet	10.0 Milligram Daily Oral
Batch:	Started: 15/09/2004 Stopped: 03/01/2005
LEVLEN ED (Other drug)	Reason: Contraception
Tablet	1.0 Dose Unspecified Daily Oral
Batch:	Started: Stopped:
Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet	8.0 Milligram Daily Oral
Batch:	Started: 22/03/2005 Stopped: 30/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

At times started to use cannabis to control paranoid feelings, but at other times she felt cannabis "made me paranoid".



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207197 **Seq:** 1 **Gender:** F
Reported: 19/04/2005 **Weight:** 0.00
Hospitalisation: Treated in Accident/Emergency Department **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle spasms		The patient developed increased muscle spasms and dystonia while on Aripiprazole.	
Dystonia			

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was also on concomitant treatment with another antipsychotic medication and was known to be susceptible to extrapyramidal symptoms in the past.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207465	Seq: 1	Gender: F
Reported: 28/04/2005		Weight: 0.00
Hospitalisation: Required a visit to the doctor		Age: 42Y
Onset Date: 01/09/2004		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vomiting Anxiety Coordination abnormal Insomnia Muscle spasms Myoclonus		Patient experienced a range of adverse reactions starting with anxiety, nausea, insomnia, muscle spasms, vomiting, myoclonus, weight loss and coordination abnormal. Patient stated "loss of control of precision muscle movements after exposure to strong chemicals".	Treatment included vitamin B12 injections, vitamin B supplements, magnesium supplements, and acupuncture.

Medicine Details:

Abilify (Suspected)		Reason: Unspecified schizophrenia	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 01/09/2004	Stopped: 01/09/2004	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient also used a hair product (non-shampoo).



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207465 **Seq:** 1 **Gender:** F
Reported: 28/04/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 42Y
Onset Date: 01/09/2004 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea Weight decreased			

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet 15.0 Milligram Daily Oral	
Batch:	Started: 01/09/2004 Stopped: 01/09/2004 0

Laboratory Investigations:

Additional Information:

The patient also used a hair product (non-shampoo).



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207470
Reported: 28/04/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paranoia	Caused or prolonged inpatient hospitalisation	Patient experienced high liver function test abnormal, creatine kinase levels and paranoia while under treatment with Aripiprazole.	Abilify discontinued. Patient self-medicated with Aripiprazole 30mg and 45mg.

Medicine Details:

Abilify (Suspected)	Reason: Unspecified neurosis
Tablet	15.0 Milligram 1 time Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207749	Seq: 1	Gender: M
Reported: 12/05/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 32
Onset Date: 15/01/2005		DOB: 11/08/1972
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Incapacity/disability	Aripiprazole initiated 20mg/day on 15/11/2004, increased to 40mg/day (prescribed overdose)	
Cellulitis	Caused or prolonged inpatient hospitalisation	The patient developed cellulitis in the legs and suspected neuroleptic malignant syndrome while on Aripiprazole. The cellulitis was severe and there was concern that amputation may be required.	
Blood creatine phosphokinase incr	Incapacity/disability		
Drug prescribing error	Incapacity/disability		

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started:
	Stopped:
LUVOX (Suspected)	Reason:
Batch:	Started: 15/11/2004
	Stopped: 17/04/2005
Abilify (Suspected)	Reason:
Tablet	Milligram
	Daily
	Oral
Batch:	Started: 15/11/2004
	Stopped: 17/04/2005
	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Neurologist suspected MacArdlesdisease with widespread myoneurosis founf on the biopsy examination



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207749 **Seq:** 1 **Gender:** M
Reported: 12/05/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 32
Onset Date: 15/01/2005 **DOB:** 11/08/1972
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
LUVOX (Suspected)	Reason:		
Batch:	Started: 15/11/2004	Stopped: 17/04/2005	
Abilify (Suspected)	Reason:		
Tablet	Milligram	Daily	Oral
Batch:	Started: 15/11/2004	Stopped: 17/04/2005	0

Laboratory Investigations:

Additional Information:

Neurologist suspected MacArdlesdisease with widespread myoneurosis founf on the biopsy examination



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207751
Reported: 12/05/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	The patient experienced suspected neuroleptic malignant syndrome while on Aripiprazole.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Developmentally delayed



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208131
Reported: 24/05/2005

Seq: 1

Gender: F
Weight: 0.00
Age: 99U

Hospitalisation:

Onset Date:
Outcome: Unknown

DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Accidental overdose		Patient experienced headaches and an overdose due to a possible dispensing error while on aripiprazole, the patient had been experiencing headaches initially with aripiprazole therapy; however, she has been doing well. Patient prescribed oral aripiprazole 10mg three times a day; however, the doctor thinks the patient may have been receiving a higher dose of aripiprazole, 20 mg three times a day, due to a possible dispensing error.	
Drug dispensing error			

Medicine Details:

Abilify (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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208131

Seq: 1

Gender: F

Reported: 24/05/2005

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Headache			

Medicine Details:

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

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208374 **Seq:** 1 **Gender:** M
Reported: 01/06/2005 **Weight:** 90.00
Hospitalisation: Required a visit to the doctor **Age:** 44
Onset Date: 28/02/2005 **DOB:** 21/10/1960
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Inability to have an erection or maintain an erection.	Withdrawal of Abilify.

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 24/02/2005 Stopped: 29/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208511
Reported: 06/06/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 23/05/2005
Outcome: Recovered

02/06/2006

Age: 29
DOB: 01/09/1975
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psoriasis	Caused or prolonged inpatient hospitalisation	Admitted to hospital with exacerbation of psoriasis. Patient started Abilify 15 mg on 09/03/05 and increased dose to 30mg on 08/04/2005. Patient noticed worsening of psoriasis, previously well controlled. Admitted to hospital on 26/05/05 with exacerbation of skin rash, widespread (over entire body) erythema, blistering, painful and itchy, fine and linear excoriations. Also developed neutropenia on admission	Cessation of aripiprazole. Oral flucloxacillin, Dermeze, Elocon, topical dressings

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram 1 time Oral
Batch:	Started: 09/03/2005 Stopped: 26/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
06/06/2005	Haematology				Neutrophil count dropped to 1.28 (1.8 to 8), WCC 2.6. CRP on admission 70 (2-10) Normalised

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208511
Reported: 06/06/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 23/05/2005
Outcome: Recovered

02/06/2006

Age: 29
DOB: 01/09/1975
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blister	Caused or prolonged inpatient hospitalisation		
Erythema	Caused or prolonged inpatient hospitalisation		
Excoriation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram 1 time Oral
Batch:	Started: 09/03/2005 Stopped: 26/05/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208511

Seq: 1

Gender: M

Reported: 06/06/2005

Weight: 0.00

Hospitalisation:

Age: 29

Onset Date: 23/05/2005

DOB: 01/09/1975

Outcome: Recovered

02/06/2006

Causality: Causality probable

Reaction Details:

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

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram 1 time Oral
Batch:	Started: 09/03/2005 Stopped: 26/05/2005

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208524 **Seq:** 1 **Gender:** M
Reported: 06/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 60Y
Onset Date: **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypertension	Incapacity/disability	Patient was switched from olanzapine to Abilify 10 mg twice daily and developed high blood pressure of 170/130 mmHg and headache.	
Headache	Incapacity/disability		

Medicine Details:

MONOPLUS NOS (Other drug)	Reason:		
Batch:	Started:	Stopped:	
Abilify (Suspected)	Reason:		
Tablet	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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208709 **Seq:** 1 **Gender:** M
Reported: 15/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 67
Onset Date: 24/05/2005 **DOB:** 25/04/1938
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Parkinsonism	Caused or prolonged inpatient hospitalisation	Patient became akinetic, psychomotor retarded, parkinsonised, cogwheel rigidity, worsening parkinsons disease, coinciding with commencing on Aripiprazole.	Aripiprazole and Carbamazepine ceased.
Cogwheel rigidity	Caused or prolonged inpatient hospitalisation		
Locked-in syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

SODIUM VALPROATE (Other drug)	Reason:	
Batch:	Started:	Stopped:
ATORVASTATIN (Other drug)	Reason: Othr&unspec metabolic diseases	
Batch:	Started:	Stopped: 0
RISPERIDONE (Other drug)	Reason: Unspecified psychosis	
Batch:	Started:	Stopped: 0
BENZYDAMINE HYDROCHLORIDE (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient history: Patient has previously been sensitive to other antipsychotics, including Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208709 **Seq:** 1 **Gender:** M
Reported: 15/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 67
Onset Date: 24/05/2005 **DOB:** 25/04/1938
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychomotor retardation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

F.G.F. (Other drug)	Reason:	
Batch:	Started:	Stopped:
METFORMIN HYDROCHLORIDE (Other drug)	Reason: Diabetes mellitus	
Batch:	Started:	Stopped: 0
CAPTOPRIL (Other drug)	Reason: Essential benign hypertension	
Batch:	Started:	Stopped: 0
GLIMEPIRIDE (Other drug)	Reason: Diabetes mellitus	
Batch:	Started:	Stopped: 0

Laboratory Investigations:

Additional Information:

Patient history: Patient has previously been sensitive to other antipsychotics, including Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208709	Seq: 1	Gender: M
Reported: 15/06/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 67
Onset Date: 24/05/2005		DOB: 25/04/1938
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Medicine Details:

ASPIRIN (Other drug)	Reason: Other coagulation defects		
Batch:	Started:	Stopped: 0	
CLONAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec		
Batch:	Started:	Stopped:	
Levodopa-Benserazide (Other drug)	Reason: Paralysis agitans		
Batch:	Started:	Stopped:	
LITHIUM CARBONATE (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 18/05/2005	Stopped: 23/05/2005	

Laboratory Investigations:

Additional Information:

Patient history: Patient has previously been sensitive to other antipsychotics, including Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208709 **Seq:** 1 **Gender:** M
Reported: 15/06/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 67
Onset Date: 24/05/2005 **DOB:** 25/04/1938
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CARBAMAZEPINE (Suspected)	Reason:
Tablet 400.0 Milligram	Daily Oral
Batch:	Started: 23/05/2005 Stopped: 25/05/2005
Aripiprazole (Suspected)	Reason: Unspecified psychosis
Tablet 10.0 Milligram	Daily Oral
Batch:	Started: 12/05/2005 Stopped: 26/05/2005

Laboratory Investigations:

Additional Information:

Patient history: Patient has previously been sensitive to other antipsychotics, including Olanzapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208789	Seq: 1	Gender: M
Reported: 20/06/2005		Weight: 0.00
Hospitalisation:		Age: 68Y
Onset Date: 24/05/2005		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation	Four days after the patient's dosage of Aripiprazole was increased to 30mg he was admitted to hospital suffering neuroleptic malignant syndrome secondary to Aripiprazole. He had combative aggressive behaviour, was incoherent, disoriented, hallucinating, had marked rigidity, twitching, tremor, increased blood pressure and fever.	Aripiprazole ceased.
Blood pressure increased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other drug)	Reason: Unspecified psychosis
40.0 Milligram	Oral
Batch:	Started: Stopped:
Levodopa-Benserazide (Other drug)	Reason: Paralysis agitans
	Oral
Batch:	Started: Stopped:
TRAMAL SR (Other drug)	Reason: Unspecified schizophrenia
400.0 Milligram	Oral
Batch:	Started: Stopped:
Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet 30.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Dose increased to 30mg 4 days before admission. Levy body dementia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208789	Seq: 1	Gender: M
Reported: 20/06/2005		Weight: 0.00
Hospitalisation:		Age: 68Y
Onset Date: 24/05/2005		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		
Incoherent	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other drug)	Reason: Unspecified psychosis
40.0 Milligram	Oral
Batch:	Started: Stopped:
Levodopa-Benserazide (Other drug)	Reason: Paralysis agitans
	Oral
Batch:	Started: Stopped:
TRAMAL SR (Other drug)	Reason: Unspecified schizophrenia
400.0 Milligram	Oral
Batch:	Started: Stopped:
Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet 30.0 Milligram	Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Dose increased to 30mg 4 days before admission. Levy body dementia.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208789
Reported: 20/06/2005
Hospitalisation:
Onset Date: 24/05/2005
Outcome: Recovered

Seq: 1

Gender: M
Weight: 0.00
Age: 68Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscle rigidity	Caused or prolonged inpatient hospitalisation		
Muscle twitching	Caused or prolonged inpatient hospitalisation		
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other drug) 40.0 Milligram Batch: Started: Stopped:	Reason: Unspecified psychosis Oral
Levodopa-Benserazide (Other drug) Batch: Started: Stopped:	Reason: Paralysis agitans Oral
TRAMAL SR (Other drug) 400.0 Milligram Batch: Started: Stopped:	Reason: Unspecified schizophrenia Oral
Aripiprazole (Suspected) Tablet 30.0 Milligram Batch: Started: Stopped:	Reason: Unspecified schizophrenia Daily Oral

Laboratory Investigations:

Additional Information:

Dose increased to 30mg 4 days before admission. Levy body dementia.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208789	Seq: 1	Gender: M
Reported: 20/06/2005		Weight: 0.00
Hospitalisation:		Age: 68Y
Onset Date: 24/05/2005		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation		
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		
Tremor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

GALANTAMINE HYDROBROMIDE (Other drug)	Reason: Unspecified psychosis
40.0 Milligram	Oral
Batch:	Started:
Batch:	Stopped:
Levodopa-Benserazide (Other drug)	Reason: Paralysis agitans
	Oral
Batch:	Started:
Batch:	Stopped:
TRAMAL SR (Other drug)	Reason: Unspecified schizophrenia
400.0 Milligram	Oral
Batch:	Started:
Batch:	Stopped:
Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet 30.0 Milligram	Daily Oral
Batch:	Started:
Batch:	Stopped:

Laboratory Investigations:

Additional Information:

Dose increased to 30mg 4 days before admission. Levy body dementia.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209181
Reported: 28/06/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 35
DOB: 29/05/1970
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		The patient experienced a raised liver function test while receiving Aripiprazole. Her ALT was reported to be 300. Other liver enzymes were two to three times the upper limit of normal.	
Alanine aminotransferase increase			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209215	Seq: 1	Gender: F
Reported: 28/06/2005		Weight: 85.00
Hospitalisation:		Age: 33
Onset Date: 23/06/2005		DOB: 01/02/1972
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rash pruritic		Onset of intense itch, prickling and bright red blotchy rash progressively getting worse each day. Affected area was the neck on both sides extending down to the collarbone area. This commenced within a couple of days after commencing a new medication (although the reaction was initially not thought to be associated with the medication). There had not been any changes e.g. in use of soaps / cleansers or other known factors. No known prior history of drug allergy.	hydrocortisone cream 1% applied since 24/06/2005 until present. The rash has settled since ceasing the suspected drug (Abilify).

Medicine Details:

PARNATE (Other drug)		Reason:	
Tablet	90.0 Milligram	2 times	Oral
Batch:	Started: 01/01/2005	Stopped:	0
NEULACTIL (Other drug)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 01/01/2005	Stopped:	0
MONOFEME 28 (Other drug)		Reason:	
Tablet	1.0	Daily	Oral
Batch:	Started: 01/11/2004	Stopped:	0
SOLIAN (Other drug)		Reason:	
Tablet	1200.0 Milligram	Daily	Oral
Batch:	Started: 01/03/2003	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209215
Reported: 28/06/2005

Seq: 1

Gender: F
Weight: 85.00

Hospitalisation:

Onset Date: 23/06/2005
Outcome: Recovered

Age: 33
DOB: 01/02/1972
Causality: Causality probable

Reaction Details:

Medicine Details:

QUILONUM SR (Other drug)	Reason:
Tablet 1350.0 Milligram	Daily Oral
Batch:	Started: 01/01/2005 Stopped:
Abilify (Suspected)	Reason:
Tablet 7.5 Milligram	Daily Oral
Batch: 521631 exp.12/2006	Started: 20/06/2005 Stopped: 25/06/2005 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209320	Seq: 1	Gender: F
Reported: 30/06/2005		Weight: 0.00
Hospitalisation:		Age: 49
Onset Date:		DOB: 25/09/1955
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Body temperature increased	Incapacity/disability	Patient experienced persistent or significant disability/incapacity symptoms of increased body temperature, feeling hot and developed headache while working in hot conditions. Symptoms resolved when patient ceased working in these conditions.	
Feeling hot	Incapacity/disability		
Headache	Incapacity/disability		

Medicine Details:

QUETIAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
NEXIUM (Other drug)	Reason:
Batch:	Started: Stopped:
Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 03/10/2003 Stopped: 05/02/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Advanced pelvic and colon cancer dx in Nove 2004.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209417	Seq: 1	Gender: M
Reported: 04/07/2005		Weight: 0.00
Hospitalisation:		Age: 69Y
Onset Date: 25/05/2005		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Delirium		The patient experienced delirium and fluctuating level of consciousness.	
Consciousness fluctuating			

Medicine Details:

MOBIC (Other drug)	Reason:
Batch:	Oral
Started:	Stopped:
REMINYL (Suspected)	Reason:
24.0 Milligram	Daily
Batch:	Oral
Started:	Stopped: 24/05/2005
MADOPAR (Suspected)	Reason:
3.0 Dose Unspecified	Daily
Batch:	Oral
Started:	Stopped: 24/05/2005
Abilify (Suspected)	Reason:
Tablet	30.0 Milligram
Batch:	Oral
Started: 17/05/2005	Stopped: 24/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of heavy body.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209417

Seq: 1

Gender: M

Reported: 04/07/2005

Weight: 0.00

Hospitalisation:

Age: 69Y

Onset Date: 25/05/2005

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Medicine Details:

TRAMADOL HYDROCHLORIDE (Suspected)

Reason:

400.0 Milligram

Daily

Oral

Batch:

Started:

Stopped: 24/05/2005

Laboratory Investigations:

Additional Information:

History of heavy body.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209673	Seq: 1	Gender: F
Reported: 11/07/2005		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
Nausea	Caused or prolonged inpatient hospitalisation	Patient experienced severe nausea and vomiting.	
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	10.0 Milligram
	1 time
	Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210099
Reported: 26/07/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 10/03/2005
Outcome: Recovered

Age: 17
DOB: 03/11/1987
Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea	Caused or prolonged inpatient hospitalisation	Patient experienced severe nausea and vomiting, dizziness, shaking, drowsiness, sensation of difficulty breathing.	Abilify was ceased.
Dizziness	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ZYPREXA (Other drug)	Reason:
Batch:	Started: 12/07/2004 Stopped:
Abilify (Suspected)	Reason: Unspecified neurosis
Tablet	10.0 Milligram Daily Oral
Batch:	Started: 10/03/2005 Stopped: 10/03/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210099
Reported: 26/07/2005

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 10/03/2005
Outcome: Recovered

Age: 17
DOB: 03/11/1987
Causality: Causality probable

Reaction Details:

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

Medicine Details:

ZYPREXA (Other drug)	Reason:		
Batch:	Started: 12/07/2004	Stopped:	
Abilify (Suspected)	Reason: Unspecified neurosis		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 10/03/2005	Stopped: 10/03/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210286 **Seq:** 1 **Gender:** F
Reported: 01/08/2005 **Weight:** 63.80
Hospitalisation: Admitted to hospital **Age:** 71
Onset Date: 16/07/2005 **DOB:** 13/03/1934
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Caused or prolonged inpatient hospitalisation	The patient's dosage of Abilify was increased from 5mg on 28 June 2005 to 10mg on 6 July 2005 to 15mg on 13 July 2005. She experienced restricted range of motion of neck movements.	Benztropine given.
Nuchal rigidity	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)	Reason:	
Batch:	Started:	Stopped:
ACIMAX (Other drug)	Reason:	
Batch:	Started:	Stopped:
FOLIC ACID (Other drug)	Reason:	
Batch:	Started:	Stopped:
FELODUR ER (Other drug)	Reason:	
Batch:	Started:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient was already in hospital at the time of reactions.
Previous history of EPSE with Risperidone and Amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210286 **Seq:** 1 **Gender:** F
Reported: 01/08/2005 **Weight:** 63.80
Hospitalisation: Admitted to hospital **Age:** 71
Onset Date: 16/07/2005 **DOB:** 13/03/1934
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

CARTIA (Other drug)		Reason:	
Batch:	Started:	Stopped:	
Abilify (Suspected)		Reason:	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 28/06/2005	Stopped: 13/07/2005	

Laboratory Investigations:

Additional Information:

Patient was already in hospital at the time of reactions.
Previous history of EPSE with Risperidone and Amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210293	Seq: 1	Gender: M
Reported: 01/08/2005		Weight: 0.00
Hospitalisation:		Age: 99U
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Patient complained that his eyes were going up and his vision was fixed on the ceiling for 2 minutes to half an hour, this occurred up to twice a week in the last couple of months.	

Medicine Details:

CLOZAPINE (Other drug)	Reason:
Batch:	Started: Stopped:
SERTRALINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
COGENTIN (Other drug)	Reason:
Batch:	Started: Stopped:
Abilify (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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210552	Seq: 1	Gender: F
Reported: 10/08/2005		Weight: 78.00
Hospitalisation: Admitted to hospital		Age: 20
Onset Date: 08/01/2005		DOB: 07/03/1984
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary retention	Caused or prolonged inpatient hospitalisation	Patient developed urinary retention.	Indwelling catheter insertion. Abilify was ceased.

Medicine Details:

FLUOXETINE HYDROCHLORIDE (Other drug)	Reason:
Batch:	Started: Stopped:
PROZAC (Other drug)	Reason:
Batch:	Started: Stopped:
PARIET (Other drug)	Reason:
Batch:	Started: Stopped:
VALIUM (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210552 **Seq:** 1 **Gender:** F
Reported: 10/08/2005 **Weight:** 78.00
Hospitalisation: Admitted to hospital **Age:** 20
Onset Date: 08/01/2005 **DOB:** 07/03/1984
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Medicine Details:

DILOSYN (Suspected)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	
Abilify (Suspected)	Reason:		
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started: 10/12/2004	Stopped: 09/01/2005	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210553	Seq: 1	Gender: M
Reported: 10/08/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 48
Onset Date: 08/07/2004		DOB: 16/08/1955
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysuria	Caused or prolonged inpatient hospitalisation	Patient developed difficulty in passing urine.	Abilify was ceased.
Urinary retention	Caused or prolonged inpatient hospitalisation		

Medicine Details:

CLOZAPINE (Suspected)		Reason: Unspecified psychosis
Tablet		Oral
Batch:	Started: 03/06/2004	Stopped: 26/07/2004
Abilify (Suspected)		Reason:
Tablet	30.0 Milligram	Daily Oral
Batch:	Started: 03/06/2004	Stopped: 26/07/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210555

Seq: 1

Gender: M

Reported: 10/08/2005

Weight: 90.00

Hospitalisation:

Age: 23

Onset Date: 01/07/2005

DOB: 19/01/1982

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Patient developed oculogyric crisis while receiving Abilify. "upward rolling movement of eye lasting 1/2 to 2 hours.	Reduce dose of Abilify to 20mg. Benztropine 1-2mg as needed.

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)	Reason:		
Tablet	Oral		
Batch:	Started:	Stopped:	
Abilify (Suspected)	Reason: Unspecified schizophrenia		
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 08/04/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210565	Seq: 1	Gender: F
Reported: 10/08/2005		Weight: 0.00
Hospitalisation: Required a visit to the doctor		Age: 57
Onset Date: 20/07/2005		DOB: 14/08/1947
Outcome: Recovered	27/07/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Rhinorrhoea Agitation Confusional state Dizziness Fear Rash Sleep disorder Vision blurred		Patient developed runny nose, blurred vision, agitated, fear, lightheaded, sleep disturbance, mental confusion, skin rash.	Beconase and Hydrocortisone cream.

Medicine Details:

SOLIAN (Other drug)	Reason: Unspecified schizophrenia
400.0 Milligram	
Batch:	Started: 01/05/2005 Stopped: 29/06/2005
ZYPREXA (Other drug)	Reason: Unspecified schizophrenia
5.0 Milligram	
Batch:	Started: Stopped: 29/06/2005
Abilify (Suspected)	Reason:
Tablet 20.0 Milligram	Daily Oral
Batch:	Started: 13/07/2005 Stopped: 26/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 211002	Seq: 1	Gender: F
Reported: 22/08/2005		Weight: 65.00
Hospitalisation:		Age: 54
Onset Date: 15/01/2005		DOB: 19/04/1950
Outcome: Recovered	15/07/2005	Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Caused or prolonged inpatient hospitalisation	The patient experienced pancreatitis while receiving Aripiprazole 60mg daily.	Aripiprazole ceased, started on Quetiapine.
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Overdose	Caused or prolonged inpatient hospitalisation		

Medicine Details:

TEMAZEPAM (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	
Batch:	Started: 01/01/2000 Stopped:
ZOLOFT (Other drug)	Reason:
Tablet 150.0 Milligram	Oral
Batch:	Started: 01/01/2000 Stopped:
Abilify (Suspected)	Reason:
Tablet 60.0 Milligram	Daily Oral
Batch:	Started: 15/10/2004 Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 211002	Seq: 1	Gender: F
Reported: 22/08/2005		Weight: 65.00
Hospitalisation:		
Onset Date: 15/01/2005		Age: 54
Outcome: Recovered	15/07/2005	DOB: 19/04/1950
		Causality: Causality possible

Reaction Details:

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

Medicine Details:

TEMAZEPAM (Other drug)	Reason: Specific disorders of sleep
10.0 Milligram	
Batch:	Started: 01/01/2000 Stopped:
ZOLOFT (Other drug)	Reason:
Tablet 150.0 Milligram	Oral
Batch:	Started: 01/01/2000 Stopped:
Abilify (Suspected)	Reason:
Tablet 60.0 Milligram	Daily Oral
Batch:	Started: 15/10/2004 Stopped: 0

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

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:

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Patient experienced tachycardia 90-110, elevated creatinine kinase reported as 246, suspected neuroleptic malignant syndrome.	Clopine withheld.
Blood creatine phosphokinase incr			
Neuroleptic malignant syndrome			
Pyrexia			

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 211097
Reported: 25/08/2005

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 08/08/2005
Outcome: Unknown

Age: 46
DOB: 27/02/1959
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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 211537 **Seq:** 1 **Gender:** F
Reported: 09/09/2005 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 43
Onset Date: 22/08/2005 **DOB:** 13/11/1961
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hallucination		Patient experienced hallucinations, disorientation, dizziness, faecal incontinence, urinary incontinence, upset stomach, palpitations.	Reduced Abilify to 30mg daily from 50mg.
Overdose		Prescribed dose above recommended	
Disorientation			
Dizziness			
Faecal incontinence			
Palpitations			
Stomach discomfort			
Urinary incontinence			

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	50.0 Milligram Daily Oral
Batch:	Started: 20/08/2005 Stopped: 01/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 211932

Seq: 1

Gender: M

Reported: 23/09/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		The patient developed neuroleptic malignant syndrome while undergoing therapy with Aripiprazole and Clozapine.	Clozapine ceased.

Medicine Details:

Abilify (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	
CLOZAPINE (Suspected)		Reason:	
Tablet			Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 212252

Seq: 1

Gender: M

Reported: 05/10/2005

Weight: 80.00

Hospitalisation:

Onset Date: 23/09/2005

Age: 36Y

Outcome: Recovered

DOB:

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia		Patient experienced severe dystonic reaction when Aripiprazole therapy changed from 10mg to 15mg daily.	
Therapy regimen changed			

Medicine Details:

LORAZEPAM (Other drug)	Reason: Otr spec symp psychopathol nec	
Tablet	6.0 Milligram	Oral
Batch:	Started: 19/09/2005	Stopped:
MIDAZOLAM (Other drug)	Reason:	
Injection	10.0 Milligram	Intramuscular
Batch:	Started: 23/09/2005	Stopped:
ZUCLOPENTHIXOL ACETATE (Suspected)	Reason: Unspecified psychosis	
Injection	150.0 Milligram	1 time Intramuscular
Batch:	Started: 23/09/2005	Stopped:
Aripiprazole (Suspected)	Reason: Unspecified psychosis	
Tablet	15.0 Milligram	Daily Oral
Batch:	Started: 19/09/2005	Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous dystonic reaction to Haloperidol.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213135
Reported: 07/11/2005

Seq: 1

Gender: F
Weight: 39.00
Age: 34
DOB: 16/03/1971
Causality: Causality possible

Hospitalisation:

Onset Date: 04/09/2005
Outcome: Recovered

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Joint stiffness	Caused or prolonged inpatient hospitalisation	Patient experienced stiff jaw and numb tongue. Previous similar reaction with Risperidone.	Given Benztropine 1mg oral.
Hypoaesthesia oral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 14/08/2005 S TERM Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous similar reaction with Risperidone.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213363

Seq: 1

Gender: F

Reported: 14/11/2005

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abortion spontaneous		The patient became pregnant while taking Aripiprazole and had a miscarriage.	

Medicine Details:

Abilify (Suspected)	Reason:	
Tablet	Oral	
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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213368	Seq: 1	Gender: F
Reported: 14/11/2005		Weight: 0.00
Hospitalisation:		Age: 37
Onset Date: 15/10/2005		DOB: 05/07/1968
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hypotension	Caused or prolonged inpatient hospitalisation	The patient was hypotensive, pale, cold and sweaty, complaining of diarrhoea and with low Oxygen levels two weeks after commencing Clozaril. She also had mild renal failure secondary to dehydration.	
Dehydration	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)	Reason:
Batch:	Started: Stopped:
AVAPRO (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet 250.0 Milligram Daily Oral	
Batch:	Started: 10/10/2005 Stopped: 24/10/2005 0
Abilify (Suspected)	Reason:
Tablet 45.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/11/2005	Creatine				360
14/11/2005	Troponin		24/10/2005	0.12	
14/11/2005	White blood cells		24/10/2005	16	pre treatment 13.4

Additional Information:

PMHx, Hypertension, Diabetes Mellitus, Increased cholesterol



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213368
Reported: 14/11/2005
Hospitalisation:
Onset Date: 15/10/2005
Outcome: Recovered

Seq: 1

Gender: F
Weight: 0.00
Age: 37
DOB: 05/07/1968
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Drug ineffective	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)	Reason:		
Batch:	Started:	Stopped:	
AVAPRO (Other drug)	Reason:		
Batch:	Started:	Stopped:	
CLOZARIL (Suspected)	Reason:		
Tablet	250.0 Milligram	Daily	Oral
Batch:	Started: 10/10/2005	Stopped: 24/10/2005	0
Abilify (Suspected)	Reason:		
Tablet	45.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Additional Information:

PMHx, Hypertension, Diabetes Mellitus, Increased cholesterol



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213368	Seq: 1	Gender: F
Reported: 14/11/2005		Weight: 0.00
Hospitalisation:		Age: 37
Onset Date: 15/10/2005		DOB: 05/07/1968
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nasopharyngitis	Caused or prolonged inpatient hospitalisation		
Oxygen saturation decreased	Caused or prolonged inpatient hospitalisation		
Pallor	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)	Reason:
Batch:	Started: Stopped:
AVAPRO (Other drug)	Reason:
Batch:	Started: Stopped:
CLOZARIL (Suspected)	Reason:
Tablet 250.0 Milligram Daily Oral	
Batch:	Started: 10/10/2005 Stopped: 24/10/2005 0
Abilify (Suspected)	Reason:
Tablet 45.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

PMHx, Hypertension, Diabetes Mellitus, Increased cholesterol



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213447	Seq: 1	Gender: F
Reported: 15/11/2005		Weight: 0.00
Hospitalisation: Admitted to hospital		Age: 20
Onset Date:		DOB: 19/09/1985
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Caused or prolonged inpatient hospitalisation	Recent increase in Aripiprazole dose form 10mg/day to 15mg/day. Actrapid-past history of antibodies to actrapid-lead to poor response to actrapid which was permanently ceased. Managed on novorapid.	Humalog IV Infusion due to actrapid ADR, Aripiprazole ceased.
Diabetic ketoacidosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

LISINOPRIL (Other drug)	Reason: Diabetes mellitus
10.0 Milligram	
Batch:	Started: Stopped:
INSULIN ASPART (Other drug)	Reason: Diabetes mellitus
Injection 3.0 Millilitre	Subcutaneous
Batch:	Started: Stopped:
INSULIN GLARGINE (Other drug)	Reason: Diabetes mellitus
Injection 10.0 Millilitre	Daily Subcutaneous
Batch:	Started: Stopped: 0
Aripiprazole (Suspected)	Reason:
Tablet 15.0 Milligram	Daily Oral
Batch:	Started: 25/10/2005 Stopped: 01/11/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213524	Seq: 1	Gender: F
Reported: 17/11/2005		Weight: 0.00
Hospitalisation:		Age: 43
Onset Date: 02/04/2005		DOB: 23/08/1961
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		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.
Blood creatine phosphokinase incr			
Hallucination, auditory			
Leukocytosis			
Pyrexia			
Suicidal ideation			

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

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:

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213524 **Seq:** 1

Gender: F

Reported: 17/11/2005

Weight: 0.00

Hospitalisation:

Age: 43

Onset Date: 02/04/2005

DOB: 23/08/1961

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

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	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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213577 **Seq:** 1 **Gender:** F
Reported: 18/11/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient developed akathisia while being treated with Aripiprazole.	Aripiprazole, Tramadol and Benzodiazepines were ceased.

Medicine Details:

TRAMAL (Suspected)	Reason:
Batch:	Started: Stopped:
Benzodiazepine NOS (Suspected)	Reason:
Batch:	Started: Stopped:
Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	10.0 Milligram Daily Oral
Batch:	Started: Stopped: 29/10/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214003 **Seq:** 1 **Gender:** U
Reported: 05/12/2005 **Weight:** 83.00
Hospitalisation: Required a visit to the doctor **Age:** 42
Onset Date: 15/05/2005 **DOB:** 10/05/1963
Outcome: Recovered 15/08/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia		The patient developed akathisia and inner restlessness, tongue and buccal movements, teeth chattering and vocal ties.	Changed to Seroquel 300mg bd.
Restlessness			

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	30.0 Milligram Daily Oral
Batch:	Started: 16/03/2005 Stopped: 08/07/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214148 **Seq:** 1 **Gender:** M
Reported: 08/12/2005 **Weight:** 0.00
Hospitalisation: Hospitalisation prolonged **Age:** 25
Onset Date: 25/10/2005 **DOB:** 05/07/1980
Outcome: Recovered 05/11/2005 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Caused or prolonged inpatient hospitalisation	The patient developed akathisia.	

Medicine Details:

Abilify (Suspected)	Reason:		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 14/10/2005	Stopped:	25/10/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Previous reaction to Risperidone.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214329 **Seq:** 1 **Gender:** F
Reported: 15/12/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 27/11/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood pressure increased	Caused or prolonged inpatient hospitalisation	Consumer reported that she experienced an allergic reaction after starting oral Abilify, her symptoms were increased blood pressure (BP was 204), agitation, anxiety, indigestion, nausea and sweating.	
Agitation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started: 17/11/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214329 **Seq:** 1 **Gender:** F
Reported: 15/12/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 27/11/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Anxiety	Caused or prolonged inpatient hospitalisation		
Dyspepsia	Caused or prolonged inpatient hospitalisation		
Hyperhidrosis	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started: 17/11/2005 Stopped:

Laboratory Investigations:

Additional Information:



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214329 **Seq:** 1 **Gender:** F
Reported: 15/12/2005 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99U
Onset Date: 27/11/2005 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

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

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started: 17/11/2005 Stopped:

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214403	Seq: 1	Gender: M
Reported: 19/12/2005		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Insomnia	Caused or prolonged inpatient hospitalisation	The patient experienced insomnia, agitation and he had stabbed himself in the neck while receiving Aripiprazole.	Benzodiazepines.
Agitation	Caused or prolonged inpatient hospitalisation		
Self mutilation	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214549

Seq: 1

Gender: M

Reported: 04/01/2006

Weight: 0.00

Hospitalisation:

Age: 19

Onset Date: 10/11/2005

DOB: 13/05/1986

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Facial palsy		Patient developed neck cramps and motor changes on the face, physician diagnosed these symptoms as Bell's palsey.	
Neck pain			

Medicine Details:

Abilify (Suspected)	Reason: Unspecified neurosis
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 09/11/2005 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214712 **Seq:** 1 **Gender:** F
Reported: 09/01/2006 **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
Agitation	Caused or prolonged inpatient hospitalisation	Patient experienced agitation which was quite bad and then she took an Abilify overdose.	Abilify was withdrawn.
Overdose	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214746

Seq: 1

Gender: F

Reported: 09/01/2006

Weight: 64.00

Hospitalisation:

Age: 40

Onset Date:

DOB: 31/07/1965

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Congenital cardiovascular anomaly		Neonate has cardiac defect requiring surgery.	
Drug exposure during pregnancy			

Medicine Details:

Aripiprazole (Suspected)	Reason: Unspecified psychosis		
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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214785	Seq: 1	Gender: M
Reported: 10/01/2006		Weight: 0.00
Hospitalisation:		Age: 69Y
Onset Date: 15/11/2005		DOB:
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		SUSPECTED - Patient was noted to have increasing creatine phosphokinase level which may be due to muscle wasting and "possibly" a " sign of neuroleptic malignant syndrome " while receiving Aripiprazole.	
Blood creatine phosphokinase incr			

Medicine Details:

CITALOPRAM HYDROBROMIDE (Other drug)		Reason: Depression
Tablet	20.0 Milligram	Daily Oral
Batch:	Started: 31/08/2001	Stopped:
Abilify (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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 215937 **Seq:** 1 **Gender:** F
Reported: 16/02/2006 **Weight:** 91.00
Hospitalisation: **Age:** 29
Onset Date: 15/11/2005 **DOB:** 12/05/1976
Outcome: Recovered 20/12/2005 **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Pateint experienced facial dyskinesia.	Abilify was ceased, Efexor XR was reduced to 150mg.

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet 30.0 Milligram Daily Oral	
Batch:	Started: 27/06/2005 Stopped: 29/11/2005 0
EFEXOR-XR (Suspected)	Reason: Unspecified schizophrenia
Capsule 300.0 Milligram Daily Oral	
Batch:	Started: 27/06/2005 Stopped: 25/07/2005 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 215962	Seq: 1	Gender: M
Reported: 17/02/2006		Weight: 0.00
Hospitalisation:		Age: 36
Onset Date: 15/02/2006		DOB: 29/08/1969
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Tachycardia - 126 bpm (Baseline pulse 80bpm) Raised Creatine Kinase - 320 Physical Exam - Normal	Observation and biochemical monitoring. CK slowly resolving. Tachycardia resolved.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		

Medicine Details:

EPILIM (Other drug)		Reason:	
Tablet	500.0 Milligram	2 times	Oral
Batch:	Started: 31/01/2006	Stopped:	
CLOPIXOL-ACUPHASE (Suspected)		Reason:	
Injection			Intramuscular
Batch:	Started: 01/02/2006	Stopped: 08/02/2006	
Abilify (Suspected)		Reason:	
Tablet	30.0 Milligram	1 time	Oral
Batch:	Started: 25/01/2006	Stopped: 15/02/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/02/2006	Creatine kinase				14/02/2006 CK - 282 15/02/2006 CK - 263

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 216020

Seq: 1

Gender: F

Reported: 20/02/2006

Weight: 70.00

Hospitalisation:

Age: 29

Onset Date: 04/02/2006

DOB: 08/04/1976

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Hyperglycaemia		Patient experienced hyperglycaemia.	

Medicine Details:

INSULIN NOS (Other drug)	Reason: Diabetes mellitus		
34.0 Unit			
Batch:	Started:	Stopped: 0	
NOVORAPID (Other drug)	Reason: Diabetes mellitus		
46.0 Unit			
Batch:	Started:	Stopped:	
Aripiprazole (Suspected)	Reason: Unspecified psychosis		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 03/02/2006	Stopped: 14/02/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 216204

Seq: 1

Gender: M

Reported: 28/02/2006

Weight: 0.00

Hospitalisation:

Age: 73Y

Onset Date:

DOB:

Outcome: Recovered

Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Patient developed grand aml seizures.	Abilify was stopped

Medicine Details:

EFEXOR (Other drug)	Reason:
150.0 Milligram	Oral
Batch:	Started:
Stopped:	
Abilify (Suspected)	Reason: Depression
Tablet	5.0 Milligram
	Daily
Batch:	Started:
Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 216287

Seq: 1

Gender: F

Reported: 07/03/2006

Weight: 0.00

Hospitalisation:

Age: 34Y

Onset Date:

DOB:

Outcome: Death, maybe drug

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient was found dead.	

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 216564	Seq: 1	Gender: M
Reported: 16/03/2006		Weight: 0.00
Hospitalisation:		Age: 25
Onset Date: 15/04/2005		DOB: 02/10/1979
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Complaining of involuntary movements of shoulder and upper chest, described as a flicking movement while he is falling asleep-> wakes him up-consistent with myclonic jerks.	
Myoclonus			

Medicine Details:

BENZTROPINE MESYLATE (Other drug)		Reason:	
	1.5 Milligram		
Batch:	Started:	Stopped:	
Aripiprazole (Suspected)		Reason: Unspecified psychosis	
Tablet	1.0 Dose Unspecified	Daily	Oral
Batch:	Started: 15/04/2005	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Describes severe side effects from previous antipsychotics, eg Quetiapine, Olanzapine and Risperidone.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 217292

Seq: 1

Gender: F

Reported: 11/04/2006

Weight: 0.00

Hospitalisation:

Age: 17Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient developed neuroleptic malignant syndrome.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

The patient was also taking multiple (unspecified) antipsychotic agents.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 217497

Seq: 1

Gender: M

Reported: 19/04/2006

Weight: 0.00

Hospitalisation:

Age: 30

Onset Date:

DOB: 12/09/1975

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Erectile dysfunction		Patient developed marked sexual side effects, particularly impotence.	Ceased Abilify.
Erectile dysfunction			

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 15/06/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Breast mass while on Risperidone and sedation while on Quetiapine.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 217649	Seq: 1	Gender: F
Reported: 24/04/2006		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Drug ineffective	Caused or prolonged inpatient hospitalisation	Patient experienced a lack of effect while being treated with Abilify.	5 months in an acute psychiatric unit.

Medicine Details:

ZOLOFT (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
CLOZAPINE (Suspected)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	30.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 217993 **Seq:** 1 **Gender:** F
Reported: 04/05/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 19
Onset Date: 30/03/2004 **DOB:** 15/07/1984
Outcome: Recovered 01/04/2004 **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Agitation	Life threatening	Agitation due to increase of Aripiprazole from 15mg on 17/3 to 30mg.	Aripiprazole ceased.
Therapy regimen changed	Life threatening		

Medicine Details:

Aripiprazole (Suspected)	Reason:
Tablet	30.0 Milligram Daily Oral
Batch:	Started: 24/03/2004 Stopped: 29/03/2004

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report 217991 is the first sequence to this report.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 218522 **Seq:** 1 **Gender:** M
Reported: 19/05/2006 **Weight:** 70.00
Hospitalisation: Treated in outpatient department only. **Age:** 30
Onset Date: 30/03/2006 **DOB:** 13/09/1975
Outcome: Recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Laryngospasm	Caused or prolonged inpatient hospitalisation	Commenced on a combination of Aripiprazole and Escitalopram. Patient developed orcho-laryngeal spasms whilst other rise tolerating the medication. This occurred whilst the patient was an outpatient.	Aripiprazole and Escitalopram withheld.

Medicine Details:

Escitalopram (Suspected)	Reason: Depression
Tablet 20.0 Milligram Daily Oral	
Batch:	Started: 15/03/2006 Stopped: 15/03/2006 0
Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet 20.0 Milligram Daily Oral	
Batch:	Started: 15/03/2006 Stopped: 15/03/2006 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient had comprimised renal function and received Lithium after withheld of the Aripiprazole and Escitalopram.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 218590

Seq: 1

Gender: M

Reported: 23/05/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Pateint experienced wildly abnormal liver function tests.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 218592

Seq: 1

Gender: F

Reported: 23/05/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Pancreatitis	Caused or prolonged inpatient hospitalisation	Pateint was hospitalised with pancreatitis while receiving Aripiprazole.	Aripiprazole withdrawn.

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219054	Seq: 1	Gender: M
Reported: 07/06/2006		Weight: 92.30
Hospitalisation:		Age: 43
Onset Date: 05/01/2006		DOB: 31/05/1962
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder		Increased dosage of Aripiprazole (15mg daily to 30mg daily), patient felt like he was "speeding". Amputated finger due to command hallucinations. Non-compliant with Olanzapine for 4 days. Possible worsening of psychosis (hallucinations) due to Aripiprazole.	Withdrawal of Aripiprazole.
Hallucination Self mutilation			

Medicine Details:

Aripiprazole (Suspected)		Reason: Unspecified schizophrenia	
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 14/12/2005	Stopped: 06/01/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219223 **Seq:** 1 **Gender:** F
Reported: 19/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: 15/05/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cyanosis	Caused or prolonged inpatient hospitalisation	Patient developed cyanosis, decreased exercise tolerance, symptoms of cardiac dysfunction, pedal edema, breathlessness, and suspected inappropriate secretion of antidiuretic hormone. About six weeks after the start of therapy, the Aripiprazole daily dose was increased from 5mg to 10mg, which is when the events began.	
Dyspnoea	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	10.0 Milligram Daily Oral
Batch:	Started: 15/03/2006 Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of Prader-Willi syndrome.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219223 **Seq:** 1 **Gender:** F
Reported: 19/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: 15/05/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Exercise tolerance decreased	Caused or prolonged inpatient hospitalisation		
Inappropriate antidiuretic hormone	Caused or prolonged inpatient hospitalisation		
Oedema peripheral	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet 10.0 Milligram Daily Oral	
Batch:	Started: 15/03/2006 Stopped:

Laboratory Investigations:

Additional Information:

History of Prader-Willi syndrome.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219223 **Seq:** 1 **Gender:** F
Reported: 19/06/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 99u
Onset Date: 15/05/2006 **DOB:**
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet 10.0 Milligram Daily Oral	
Batch:	Started: 15/03/2006 Stopped:

Laboratory Investigations:

Additional Information:

History of Prader-Willi syndrome.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219323	Seq: 1	Gender: F
Reported: 20/06/2006		Weight: 69.00
Hospitalisation: Required a visit to the doctor		Age: 58
Onset Date: 13/04/2006		DOB: 23/05/1947
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Low density lipoprotein increased		Rise in LDL level when switched from Olazapine to Abilify.	Nil.

Medicine Details:

ATORVASTATIN (Other drug)	Reason: Othr&unspec metabolic diseases
Tablet	40.0 Milligram
	Oral
Batch:	Started: 15/05/2005
	Stopped:
EFEXOR-XR (Other drug)	Reason: Depression
Capsule, modified release	300.0 Milligram
	Oral
Batch:	Started:
	Stopped:
Abilify (Suspected)	Reason: Manic depressive psycho, depre
Tablet	10.0 Milligram
	Daily
	Oral
Batch:	Started: 10/04/2006
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219616
Reported: 03/07/2006

Seq: 1

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Recovered

Age: 33
DOB: 22/12/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Convulsive threshold lowered		Patient experienced a decrease in the seizure threshold.	

Medicine Details:

CARBAMAZEPINE (Other drug)	Reason: Convulsions		
Batch:	Started:	Stopped:	
Abilify (Suspected)	Reason: Unspecified psychosis		
Tablet	30.0 Milligram	Daily	Oral
Batch:	Started: 09/11/2005	Stopped:	0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219840

Seq: 1

Gender: M

Reported: 10/07/2006

Weight: 0.00

Hospitalisation:

Age: 34Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Condition aggravated		Patient had suffered an increasingly psychotic state with an increase in his auditory hallucinations and paranoid ideation.	Abilify discontinued.

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Daily Oral
Batch:	Started: Stopped: 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Chronic paranoid schizophrenia, anxiety, smoker and overweight.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219844	Seq: 1	Gender: M
Reported: 10/07/2006		Weight: 0.00
Hospitalisation:		Age: 34Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular		Patient had shown a dilated left ventricle with mild to moderate left ventricular systolic dysfunction.	Abilify discontinued
Ventricular dysfunction			

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	Oral
Batch:	Started:
Batch:	Stopped:
CLOZARIL (Suspected)	Reason: Unspecified schizophrenia
Tablet	650.0 Milligram Daily Oral
Batch:	Started:
Batch:	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History: Chronic paranoid shizophrenia, anxiety, depression, smoker and overweight.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 220455 **Seq:** 1 **Gender:** M
Reported: 31/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 19
Onset Date: 18/11/2004 **DOB:** 20/07/1985
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Somnolence		Patient stopped Abilify because of drowsiness.	

Medicine Details:

CANNABIS PREPARATION (Other drug)	Reason:		
Batch:	Started:	Stopped:	
DEXAMPHETAMINE SULPHATE (Other drug)	Reason:		
Batch:	Started:	Stopped:	
Abilify (Suspected)	Reason: Unspecified psychosis		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 25/03/2004	Stopped: 18/11/2004	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Neurologist Diagnosis: Autistic spectrum disorder and iatrogenic Tardive Dyskinesia. Reduced IQ secondary to birth hypoxia (mild intellectual impairment).
Report 220456 is the second sequence to this report and 220457 is the third sequence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 220457 **Seq:** 1 **Gender:** M
Reported: 31/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20
Onset Date: 06/09/2005 **DOB:** 20/07/1985
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia	Caused or prolonged inpatient hospitalisation	Patient experienced akathisia, marked involuntary movements evident in arms and legs, increased agitation, whilst walking, jerking of right upper limb++. Jerky flexion of knees on each steps slows walk. Involuntary movements then feels stiffness in calves and wants to sit down. Excessive salivation, choreiform movements, increased aggressive behaviours.	Quetiapine, Propranolol, Lorazepam 1mg tds for 2 days,

Medicine Details:

Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 25/03/2004 Stopped: 30/09/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Neurologist Diagnosis: Autistic spectrum disorder and iatrogenic Tardis Dyskinesia. Reduced IQ secondary to birth hypoxia (mild intellectual impairment).
Report 220455 is the first sequence to this report and 220456 the second sequence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 220457 **Seq:** 1 **Gender:** M
Reported: 31/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20
Onset Date: 06/09/2005 **DOB:** 20/07/1985
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Aggression	Caused or prolonged inpatient hospitalisation		
Agitation	Caused or prolonged inpatient hospitalisation		
Akathisia	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 25/03/2004 Stopped: 30/09/2005

Laboratory Investigations:

Additional Information:

Neurologist Diagnosis: Autistic spectrum disorder and iatrogenic Tardis Dyskinesia. Reduced IQ secondary to birth hypoxia (mild intellectual impairment).
Report 220455 is the first sequence to this report and 220456 the second sequence.



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 220457 **Seq:** 1 **Gender:** M
Reported: 31/07/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 20
Onset Date: 06/09/2005 **DOB:** 20/07/1985
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Chorea	Caused or prolonged inpatient hospitalisation		
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason: Unspecified psychosis
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 25/03/2004 Stopped: 30/09/2005

Laboratory Investigations:

Additional Information:

Neurologist Diagnosis: Autistic spectrum disorder and iatrogenic Tardis Dyskinesia. Reduced IQ secondary to birth hypoxia (mild intellectual impairment).
Report 220455 is the first sequence to this report and 220456 the second sequence.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 220752	Seq: 1	Gender: F
Reported: 14/08/2006		Weight: 55.00
Hospitalisation:		Age: 39
Onset Date: 10/06/2006		DOB: 20/04/1967
Outcome: Recovered	06/07/2006	Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase incr	Life threatening	Hypertonia in all limbs, frequent and small amount urine, temp 37.8C, decreased speech - almost mute and possible neuroleptic malignant syndrome.	
Body temperature increased	Life threatening		
Hypertonia	Life threatening		
Neuroleptic malignant syndrome	Life threatening		
Pollakiuria	Life threatening		

Medicine Details:

Aripiprazole (Suspected)		Reason: Unspecified psychosis	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started: 19/05/2006	Stopped: 10/06/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
14/08/2006	Creatine				Increased CK to 900.

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 222427

Seq: 1

Gender: F

Reported: 13/10/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Vision blurred		Eye problems (focus is off, hard to see the whole picture, kind of get stuck and muscles might be stiff), stomach pains and chest pains.	
Abdominal pain upper			
Chest pain			

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 222500

Seq: 1

Gender: M

Reported: 16/10/2006

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Diabetes mellitus.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 223733	Seq: 1	Gender: M
Reported: 04/12/2006		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Feeling of despair		Patient had feelings of despair, depression, akathisia.	
Akathisia			
Depression			

Medicine Details:

SEROQUEL (Suspected)	Reason:
Batch:	Started:
	Stopped:
Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	45.0 Milligram Daily Oral
Batch:	Started:
	Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 223788

Seq: 1

Gender: M

Reported: 05/12/2006

Weight: 101.00

Hospitalisation:

Age: 43

Onset Date:

DOB: 25/04/1963

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Akathisia	Life threatening	Previously taken oral risperidone and tolerated well, however, depot had never been given before. Patient became akathesic with aripiprazole.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 224201 **Seq:** 1 **Gender:** M
Reported: 19/12/2006 **Weight:** 0.00
Hospitalisation: Admitted to hospital **Age:** 70Y
Onset Date: **DOB:**
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening	Cardiac arrest.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Prior to the start of the aripiprazole therapy, the patient was admitted to the hospital while receiving risperidone. He was then switched to aripiprazole 10mg, and within 24 hours had experienced cardiac arrest. Medical history: included cardiovascular disease.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 224753 **Seq:** 1 **Gender:** F
Reported: 17/01/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 37
Onset Date: 06/12/2006 **DOB:** 20/08/1969
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Nausea Urticaria Vomiting		Nausea, vomiting and facial rash.	Moxolon and phenergan.

Medicine Details:

Abilify (Suspected)	Reason: Unspecified schizophrenia
Tablet	10.0 Milligram Daily Oral
Batch:	Started: 06/12/2006 Stopped: 06/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 224786 **Seq:** 1 **Gender:** F
Reported: 17/01/2007 **Weight:** 0.00
Hospitalisation: Required a visit to the doctor **Age:** 37
Onset Date: 05/12/2006 **DOB:** 20/08/1969
Outcome: Not yet recovered **Causality:** Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Abdominal pain Nausea Rash Vomiting		Two hours after intergestion developed abdominal pain, nausea, vomiting, skin rashes at the face and neck.	

Medicine Details:

Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet	10.0 Milligram Daily Oral
Batch:	Started: 05/12/2006 Stopped: 05/12/2006

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 224812

Seq: 1

Gender: F

Reported: 18/01/2007

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Muscular weakness	Caused or prolonged inpatient hospitalisation	Patient experienced weakness in her legs, an inability to walk, difficulty with words and stumbling.	
Dysphasia	Caused or prolonged inpatient hospitalisation		
Dysuria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 224812

Seq: 1

Gender: F

Reported: 18/01/2007

Weight: 0.00

Hospitalisation:

Age: 99u

Onset Date:

DOB:

Outcome: Not yet recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Gait disturbance	Caused or prolonged inpatient hospitalisation		

Medicine Details:

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

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 224834 **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
Abnormal behaviour	Caused or prolonged inpatient hospitalisation	behaviour problems escalated.	Risperidone 1mg was reintroduced but her movement disorder worsened again so risperidone was subsequently discontinued.

Medicine Details:

Aripiprazole (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 problems.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 225099	Seq: 1	Gender: M
Reported: 25/01/2007		Weight: 0.00
Hospitalisation:		Age: 21
Onset Date: 02/11/2006		DOB: 29/11/1984
Outcome: Recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia	Incapacity/disability	Patient experienced a severe dystonic reaction while receiving Abilify, patient's creatinine kinase level reached 2800, was not able to walk due to severe cramps, not being able to control movement in hands and feet, swollen tongue and an arched back.	Ceased Abilify, treated with 2mg IM Inject of benztropine.
Blood creatine phosphokinase incr	Incapacity/disability		
Muscle spasms	Incapacity/disability		
Opisthotonus	Incapacity/disability		

Medicine Details:

Abilify (Suspected)		Reason: Othr&unspec metabolic diseases	
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 02/11/2006	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
25/01/2007	Creatine				Creatinine Kinase - 2800

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 225099

Seq: 1

Gender: M

Reported: 25/01/2007

Weight: 0.00

Hospitalisation:

Age: 21

Onset Date: 02/11/2006

DOB: 29/11/1984

Outcome: Recovered

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Swollen tongue	Incapacity/disability		

Medicine Details:

Abilify (Suspected)	Reason: Othr&unspec metabolic diseases		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 02/11/2006	

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 225141	Seq: 1	Gender: M
Reported: 29/01/2007		Weight: 0.00
Hospitalisation:		Age: 62Y
Onset Date: 10/11/2006		DOB:
Outcome: Not yet recovered		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia	Caused or prolonged inpatient hospitalisation	Sinus tachycardia, tightness back and neck.	Commenced bisoprolol.
Back pain	Caused or prolonged inpatient hospitalisation		
Neck pain	Caused or prolonged inpatient hospitalisation		

Medicine Details:

ATORVASTATIN (Other drug)	Reason:
80.0 Milligram	
Batch:	Started: Stopped:
SODIUM VALPROATE (Other drug)	Reason:
Batch:	Started: Stopped:
FRUSEMIDE (Other drug)	Reason:
Batch:	Started: Stopped:
IRBESARTAN (Other drug)	Reason:
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 225141 **Seq:** 1
Reported: 29/01/2007

Gender: M
Weight: 0.00

Hospitalisation:

Onset Date: 10/11/2006
Outcome: Not yet recovered

Age: 62Y
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

ASPIRIN (Other drug)	Reason:
Batch:	Started: Stopped:
Seretide 500/50 Accuhaler (Other drug)	Reason:
Batch:	Started: Stopped:
Aripiprazole (Suspected)	Reason:
Tablet	5.0 Milligram Daily Oral
Batch:	Started: 09/11/2006 Stopped: 11/11/2006

Laboratory Investigations:

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 225382 **Seq:** 1 **Gender:** M
Reported: 02/02/2007 **Weight:** 95.00
Hospitalisation: Required a visit to the doctor **Age:** 21
Onset Date: 04/01/2007 **DOB:** 18/11/1985
Outcome: Not yet recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia		Development of oro- buccal dyskinesia- low grade. Grade low- noticed by patient & girlfriend release phenoma present.	

Medicine Details:

RISPERIDONE (Suspected)	Reason:		
Batch:	Started:	Stopped:	
AMISULPRIDE (Suspected)	Reason:		
Batch:	Started:	Stopped: 0	
Abilify (Suspected)	Reason: Othr&unspec metabolic diseases		
Tablet	15.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past exposure to other antipsychotics-risperidone, amisulpride.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 225784	Seq: 1	Gender: F
Reported: 13/02/2007		Weight: 0.00
Hospitalisation:		Age: 16Y
Onset Date:		DOB:
Outcome: Unknown		Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Full blood count decreased	Caused or prolonged inpatient hospitalisation	Blood count and Neutrophils had decreased.	Aripiprazole ceased.
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 226316	Seq: 1	Gender: F
Reported: 05/03/2007		Weight: 0.00
Hospitalisation:		Age: 99u
Onset Date:		DOB:
Outcome: Not yet recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient's symptoms included trouble talking, muscle rigidity, muscle weakness and elevated creatine kinase.	Abilify discontinued.
Blood creatine phosphokinase incr	Caused or prolonged inpatient hospitalisation		
Speech disorder	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Abilify (Suspected)	Reason:
Tablet	15.0 Milligram Daily Oral
Batch:	Started: 29/01/2007 Stopped: 05/02/2007

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 226616	Seq: 1	Gender: M
Reported: 14/03/2007		Weight: 51.00
Hospitalisation:		Age: 12
Onset Date:		DOB: 02/02/1995
Outcome: Recovered		Causality: Causality probable

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Urinary incontinence, sleep excessive, vagueness.	
Confusional state			
Hypersomnia			

Medicine Details:

DEXAMPHETAMINE SULPHATE (Other drug)		Reason: Behavior disorders of childhood	
	10.0 Milligram	Daily	
Batch:	Started:	Stopped:	15/01/2007
Aripiprazole (Suspected)		Reason:	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	15/01/2007 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Taken off medication when custody given to father, urinary incontinence stopped within 1 week of stopping, remains dry 1 month later.



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 226805

Seq: 1

Gender: M

Reported: 21/03/2007

Weight: 0.00

Hospitalisation:

Age: 28Y

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eye rolling		Patient's eyes were "rolling in back of head" while receiving aripiprazole.	

Medicine Details:

Abilify (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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 226806
Reported: 21/03/2007

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date:
Outcome: Unknown

Age: 21Y
DOB:
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Eye rolling		Patient experienced her eyes rolling back in her head while taking 30 mg of aripiprazole daily.	

Medicine Details:

Lexapro (Other drug)	Reason:
Tablet	Oral
Batch:	Started: Stopped:
Abilify (Suspected)	Reason:
Tablet	30.0 Milligram Daily Oral
Batch:	Started: Stopped:

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Patient is of Aboriginal descent had not experienced problems with her sight.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 226926
Reported: 23/03/2007

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 05/12/2006
Outcome: Recovered

Age: 33
DOB: 03/07/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Paraesthesia	Caused or prolonged inpatient hospitalisation	Patient had symptoms of pins and needles which started on Fluoxetine and worsened when Aripiprazole was added on as a second treatment. Other symptoms were: word finding difficulty, dysarthriatic speech, weakness of the lower limbs with a tendency to falls.	Stopping Aripiprazole
Dysarthria	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Suspected)		Reason: Unspecified schizophrenia	
Tablet	10.0 Milligram	Daily	Oral
Batch:	Started:	Stopped: 19/12/2006	
FLUVOXAMINE MALEATE (Suspected)		Reason: Unspecified schizophrenia	
Tablet	100.0 Milligram	Daily	Oral
Batch:	Started:	Stopped:	

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Fluvoxamine is a cxb3A4 inhibitor (moderate) so may have increased Aripiprazole levels.



Therapeutic Goods Administration Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 226926
Reported: 23/03/2007

Seq: 1

Gender: F
Weight: 0.00

Hospitalisation:

Onset Date: 05/12/2006
Outcome: Recovered

Age: 33
DOB: 03/07/1973
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dysphasia	Caused or prolonged inpatient hospitalisation		
Fall	Caused or prolonged inpatient hospitalisation		
Muscular weakness	Caused or prolonged inpatient hospitalisation		

Medicine Details:

Aripiprazole (Suspected)	Reason: Unspecified schizophrenia
Tablet 10.0 Milligram Daily Oral	
Batch:	Started: Stopped: 19/12/2006
FLUVOXAMINE MALEATE (Suspected)	Reason: Unspecified schizophrenia
Tablet 100.0 Milligram Daily Oral	
Batch:	Started: Stopped:

Laboratory Investigations:

Additional Information:

Fluvoxamine is a cxb3A4 inhibitor (moderate) so may have increased Aripiprazole levels.



THERAPEUTIC GOODS ADMINISTRATION Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 227326

Seq: 1

Gender: F

Reported: 04/04/2007

Weight: 0.00

Hospitalisation:

Age: 99U

Onset Date:

DOB:

Outcome: Unknown

Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Oculogyration		Oculogyration	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:



THERAPEUTIC GOODS ADMINISTRATION

Public Case Detail

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

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:

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.