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.

Report Details:

Case Number: 187879 **Seq:** 1 **Gender:** M
Reported: 27/06/2003 **Weight:** 90.00
Hospitalisation: **Age:** 36
Onset Date: 23/06/2003 **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:

Report Details:

Case Number: 191364 **Seq:** 1 **Gender:** M
Reported: 16/10/2003 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:**
Outcome: Recovered **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.

Report Details:

Case Number: 192069 **Seq:** 1
Reported: 11/11/2003
Hospitalisation: Admitted to hospital
Onset Date: 07/10/2003
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 30
DOB:
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.

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 192275 **Seq:** 1 **Gender:** F
Reported: 17/11/2003 **Weight:** 0.00
Hospitalisation: **Age:** 56
Onset Date: 30/10/2003 **DOB:** 03/08/1947
Outcome: Recovered **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:

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.

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.

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, deliriouss, 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:

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:

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:

Report Details:

Case Number: 192487 **Seq:** 1
Reported: 25/11/2003
Hospitalisation: Admitted to hospital
Onset Date: 25/09/2003
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 50
DOB:
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 low	
25/11/2003	Chloride		14/10/2003	88 MMOL/L low	
25/11/2003	Creatinine		08/10/2003	58 MMOL/L low	
25/11/2003	Creatinine		14/10/2003	70 MMOL/L low	
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.

Report Details:

Case Number: 192487 **Seq:** 1
Reported: 25/11/2003
Hospitalisation: Admitted to hospital
Onset Date: 25/09/2003
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 50
DOB:
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.

Report Details:

Case Number: 192487 **Seq:** 1
Reported: 25/11/2003
Hospitalisation: Admitted to hospital
Onset Date: 25/09/2003
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 50
DOB:
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.

Report Details:

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

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

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:

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

Report Details:

Case Number: 193937 **Seq:** 1
Reported: 16/01/2004
Hospitalisation: Admitted to hospital
Onset Date: 10/12/2003
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 19
DOB:
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.

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:

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:

Report Details:

Case Number: 194604 **Seq:** 1 **Gender:** F
Reported: 16/02/2004 **Weight:** 0.00
Hospitalisation: **Age:** 34
Onset Date: 09/02/2004 **DOB:** 21/08/1969
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dystonia Tongue oedema	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.

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.

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 Blood creatine phosphokinase incr Hyperhidrosis Hyperreflexia Mood swings Muscle rigidity Pyrexia Tachycardia		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.

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 phosphokinase		01/01/2004	61	
04/03/2004	Creatine phosphokinase		22/01/2004	356	
04/03/2004	Creatine phosphokinase		26/01/2004	238	

Additional Information:

Patient also administered: Sodium valproate, Clonazepam.

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.

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.

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.

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 Drug interaction		Hypotensive (66/26).	Aripiprazole withheld then ceased. IV fluids given but was hard to re-establish BP.

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.

Report Details:

Case Number: 196570 **Seq:** 1 **Gender:** M
Reported: 19/04/2004 **Weight:** 70.00
Hospitalisation: **Age:** 52
Onset Date: 22/03/2004 **DOB:** 02/01/1952
Outcome: Recovered **Causality:** Causality probable

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:

Report Details:

Case Number: 196781 **Seq:** 1
Reported: 23/04/2004
Hospitalisation: Hospitalisation prolonged
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 56
DOB:
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:

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:

Report Details:

Case Number: 197298 **Seq:** 1
Reported: 12/05/2004
Hospitalisation:
Onset Date: 27/12/2003
Outcome: Death, maybe drug

Gender: F
Weight: 0.00
Age: 24Y
DOB:
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.

Report Details:

Case Number: 197651 **Seq:** 1
Reported: 27/05/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99u
DOB:
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:

Report Details:

Case Number: 197656 **Seq:** 1
Reported: 27/05/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 34Y
DOB:
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:

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.

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:

Report Details:

Case Number: 198644 **Seq:** 1
Reported: 02/07/2004
Hospitalisation:
Onset Date: 15/06/2004
Outcome: Not yet recovered

Gender: M
Weight: 55.00
Age: 28
DOB: 27/12/1975
Causality: Causality possible

Reaction Details:

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

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.

Report Details:

Case Number: 198989 **Seq:** 1
Reported: 16/07/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99U
DOB:
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.

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:**

Oral

Batch: **Started:** S TERM **Stopped:** Contin

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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 Dizziness Fatigue Malaise		Arrhythmia, dizziness, fatigue and 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.

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 phosphokinase	(N=25-150)	13/07/2004	217	
02/08/2004	Creatine phosphokinase	(N=25-150)	27/07/2004	136	

Additional Information:

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

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
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:

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

Report Details:

Case Number: 199795 **Seq:** 1
Reported: 09/08/2004
Hospitalisation: Treated in Accident/Emergency Department
Onset Date: 01/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 34Y
DOB:
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 (hypothyrpidism)

Report Details:

Case Number: 199795 **Seq:** 1
Reported: 09/08/2004
Hospitalisation: Treated in Accident/Emergency Department
Onset Date: 01/07/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 34Y
DOB:
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 (hypothyrpidism)

Report Details:

Case Number: 199812 **Seq:** 1
Reported: 10/08/2004
Hospitalisation:
Onset Date: 24/06/2004
Outcome: Recovered without treatment

Gender: F
Weight: 0.00
Age: 47
DOB: 18/08/1956
Causality: Causality possible

Reaction Details:

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

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:

Report Details:

Case Number: 200145 **Seq:** 1
Reported: 19/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 19Y
DOB:
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 phosphokinase				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:

Report Details:

Case Number: 200145 **Seq:** 1
Reported: 19/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 19Y
DOB:
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:

Report Details:

Case Number: 200145 **Seq:** 1
Reported: 19/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 19Y
DOB:
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:

Report Details:

Case Number: 200145 **Seq:** 1
Reported: 19/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 19Y
DOB:
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:

Report Details:

Case Number: 200145 **Seq:** 1
Reported: 19/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 19Y
DOB:
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:

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:

Report Details:

Case Number: 200429 **Seq:** 1
Reported: 30/08/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 21
DOB:
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:

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 Aripipazole 15mg, the symptoms subsided. When the dose was increased to 20mg, the TD returned. The dose has since been decreased to 15mg.

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. Histrory of: diabetes mellitus, myocardial ischaemia, hypertension, smoker, blood cholesterol increased.

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 Galactorrhoea		Ammenonhea (2 periods missed) and lactation.	

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:

Report Details:

Case Number: 201058 **Seq:** 1
Reported: 22/09/2004
Hospitalisation: Admitted to hospital
Onset Date: 15/08/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 20
DOB:
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 schizoaffective 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:

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:

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:

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 Hiccups		Patient developed restlessness unable to sit still, and hiccups.	Ceased Abilify

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:

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:

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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 202406 **Seq:** 1
Reported: 09/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 06/10/2004
Outcome: Unknown

Gender: M
Weight: 105.00
Age: 29
DOB: 21/07/1975
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 phosphokinase		06/10/2004	3770	
09/11/2004	Creatine phosphokinase		07/10/2004	9840	
09/11/2004	Creatine phosphokinase		08/10/2004	8000	
09/11/2004	Creatine phosphokinase		09/10/2004	3160	
09/11/2004	Creatine phosphokinase		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.

Report Details:

Case Number: 202406 **Seq:** 1
Reported: 09/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 06/10/2004
Outcome: Unknown

Gender: M
Weight: 105.00
Age: 29
DOB: 21/07/1975
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.

Report Details:

Case Number: 202406 **Seq:** 1
Reported: 09/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 06/10/2004
Outcome: Unknown

Gender: M
Weight: 105.00
Age: 29
DOB: 21/07/1975
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.

Report Details:

Case Number: 202406 **Seq:** 1
Reported: 09/11/2004
Hospitalisation: Admitted to hospital
Onset Date: 06/10/2004
Outcome: Unknown

Gender: M
Weight: 105.00
Age: 29
DOB: 21/07/1975
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:** **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.

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, recoeverd 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:

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:

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:

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:

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:

Report Details:

Case Number: 203073 **Seq:** 1
Reported: 25/11/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: M
Weight: 72.00
Age: 28Y
DOB:
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:

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.

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.

Report Details:

Case Number: 203122 **Seq:** 1
Reported: 29/11/2004
Hospitalisation:
Onset Date: 14/10/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 25
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 prominant 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.

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 restles 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.

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 Corneal reflex decreased Dyskinesia Muscle spasms		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.

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.

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:

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:

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:

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:

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:

Report Details:

Case Number: 203689 **Seq:** 1
Reported: 21/12/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
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:** **Stopped:**

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

LITHIUM CARBONATE (Other drug) **Reason:**
Tablet Oral
Batch: **Started:** **Stopped:**

Abilify (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 08/11/2004 **Stopped:**

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Report Details:

Case Number: 203689 **Seq:** 1
Reported: 21/12/2004
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 99u
DOB:
Causality: Causality possible

Reaction Details:

Medicine Details:

HALOPERIDOL (Suspected) **Reason:**

8.0 Milligram Daily Oral

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

Laboratory Investigations:

Additional Information:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 203840 **Seq:** 1
Reported: 30/12/2004
Hospitalisation:
Onset Date: 16/12/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 41
DOB: 09/12/1963
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:

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:

Report Details:

Case Number: 204033 **Seq:** 1
Reported: 10/01/2005
Hospitalisation: Admitted to hospital
Onset Date: 12/11/2004
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 63Y
DOB:
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:

Report Details:

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

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 Akathisia		The patient experienced severe Parkinsonian with extrapyramidal side effects and akathisia.	Benztropine ceased.

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:

Report Details:

Case Number: 204250 **Seq:** 1
Reported: 14/01/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 99U
DOB:
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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204340 **Seq:** 1 **Gender:** M
Reported: 18/01/2005 **Weight:** 110.00
Hospitalisation: **Age:** 26
Onset Date: 20/09/2004 **DOB:**
Outcome: Unknown **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 excesive 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:

Report Details:

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 204828 **Seq:** 1
Reported: 02/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 22/11/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 40
DOB:
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:

Report Details:

Case Number: 204828 **Seq:** 1
Reported: 02/02/2005
Hospitalisation: Admitted to hospital
Onset Date: 22/11/2004
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 40
DOB:
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:

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.

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 Oral
Batch: **Started:** 05/10/2004 **Stopped:** 15/01/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Past history schizophernia, PTSD and depression but never manic.

Report Details:

Case Number: 205444 **Seq:** 1 **Gender:** M
Reported: 22/02/2005 **Weight:** 142.00
Hospitalisation: **Age:** 28
Onset Date: 10/12/2004 **DOB:**
Outcome: Recovered **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.

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 Respiridone 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.

Report Details:

Case Number: 205845 **Seq:** 1 **Gender:** M
Reported: 08/03/2005 **Weight:** 0.00
Hospitalisation: **Age:** 43
Onset Date: 31/01/2005 **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:

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 Tremor		The patient experienced extreme agitation and a marked tremor.	Settled with ceasing Abilify and Benzodiazepam.

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:

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 Drug ineffective		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.

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:

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 Anxiety Muscle rigidity		The patient developed a shuffling, unsteady gait. Very anxious and unwilling to walk unless necessary. Rigidity of the limbs.	Abilify and Lexapro ceased.

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:

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.

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.

Report Details:

Case Number: 206963 **Seq:** 1 **Gender:** F
Reported: 13/04/2005 **Weight:** 93.00
Hospitalisation: **Age:** 28
Onset Date: 20/03/2005 **DOB:** 02/04/1976
Outcome: Recovered 04/04/2005 **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:

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 Akathisia Somnolence		Patient experienced restless limbs - feeling of 'blood flowing up and down arms' and restless, subjective feelings, drowsiness and akathesia.	Aripiprazole ceased. Treated with Bentropine.

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".

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 Dystonia		The patient developed increased muscle spasms and dystonia while on 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:

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207465 **Seq:** 1
Reported: 28/04/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 01/09/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 42Y
DOB:
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).

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207465 **Seq:** 1
Reported: 28/04/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 01/09/2004
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 42Y
DOB:
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).

Report Details:

Case Number: 207470 **Seq:** 1 **Gender:** M
Reported: 28/04/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207749 **Seq:** 1
Reported: 12/05/2005
Hospitalisation: Admitted to hospital
Onset Date: 15/01/2005
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 32
DOB: 11/08/1972
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Therapy regimen changed	Incapacity/disability	Aripriprazole 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

Report Details:

Case Number: 207749 **Seq:** 1
Reported: 12/05/2005
Hospitalisation: Admitted to hospital
Onset Date: 15/01/2005
Outcome: Unknown

Gender: M
Weight: 0.00
Age: 32
DOB: 11/08/1972
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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 207751 **Seq:** 1 **Gender:** F
Reported: 12/05/2005 **Weight:** 0.00
Hospitalisation: **Age:** 99u
Onset Date: **DOB:**
Outcome: Unknown **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:

Developementaly delayed

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
Accidental overdose Drug dispensing error		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 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.	

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:

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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 208374 **Seq:** 1
Reported: 01/06/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 28/02/2005
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 44
DOB: 21/10/1960
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:

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
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 coint dropped to 1.28 (1.8 to 8), WCC 2.6. CRP on admission 70 (2-10) Normalised

Additional Information:

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
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:

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:

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:

Report Details:

Case Number: 208709 **Seq:** 1
Reported: 15/06/2005
Hospitalisation: Admitted to hospital
Onset Date: 24/05/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 67
DOB: 25/04/1938
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, conciding 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.

Report Details:

Case Number: 208709 **Seq:** 1
Reported: 15/06/2005
Hospitalisation: Admitted to hospital
Onset Date: 24/05/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 67
DOB: 25/04/1938
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.

Report Details:

Case Number: 208709 **Seq:** 1
Reported: 15/06/2005
Hospitalisation: Admitted to hospital
Onset Date: 24/05/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 67
DOB: 25/04/1938
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.

Report Details:

Case Number: 208709 **Seq:** 1
Reported: 15/06/2005
Hospitalisation: Admitted to hospital
Onset Date: 24/05/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 67
DOB: 25/04/1938
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.

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.

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.

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
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) **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.

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:** **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.

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209181 **Seq:** 1 **Gender:** F
Reported: 28/06/2005 **Weight:** 0.00
Hospitalisation: **Age:** 35
Onset Date: **DOB:** 29/05/1970
Outcome: Unknown **Causality:** Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal Alanine aminotransferase increase		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.	

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:

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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 209215 **Seq:** 1
Reported: 28/06/2005
Hospitalisation:
Onset Date: 23/06/2005
Outcome: Recovered

Gender: F
Weight: 85.00
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:

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.

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 Consciousness fluctuating		The patient experienced delirium and fluctuating level of consciousness.	

Medicine Details:

MOBIC (Other drug) **Reason:**
Oral
Batch: **Started:** **Stopped:**

REMINYL (Suspected) **Reason:**
24.0 Milligram Daily Oral
Batch: **Started:** **Stopped:** 24/05/2005

MADOPAR (Suspected) **Reason:**
3.0 Dose Unspecified Daily Oral
Batch: **Started:** **Stopped:** 24/05/2005

Abilify (Suspected) **Reason:**
Tablet 30.0 Milligram Daily Oral
Batch: **Started:** 17/05/2005 **Stopped:** 24/05/2005

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

History of heavy body.

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.

Report Details:

Case Number: 209673 **Seq:** 1
Reported: 11/07/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99u
DOB:
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:

Report Details:

Case Number: 210099 **Seq:** 1 **Gender:** F
Reported: 26/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 17
Onset Date: 10/03/2005 **DOB:** 03/11/1987
Outcome: Recovered **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:

Report Details:

Case Number: 210099 **Seq:** 1 **Gender:** F
Reported: 26/07/2005 **Weight:** 0.00
Hospitalisation: **Age:** 17
Onset Date: 10/03/2005 **DOB:** 03/11/1987
Outcome: Recovered **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:

Report Details:

Case Number: 210286 **Seq:** 1
Reported: 01/08/2005
Hospitalisation: Admitted to hospital
Onset Date: 16/07/2005
Outcome: Recovered

Gender: F
Weight: 63.80
Age: 71
DOB: 13/03/1934
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.

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210286 **Seq:** 1
Reported: 01/08/2005
Hospitalisation: Admitted to hospital
Onset Date: 16/07/2005
Outcome: Recovered

Gender: F
Weight: 63.80
Age: 71
DOB: 13/03/1934
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.

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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210552 **Seq:** 1
Reported: 10/08/2005
Hospitalisation: Admitted to hospital
Onset Date: 08/01/2005
Outcome: Recovered

Gender: F
Weight: 78.00
Age: 20
DOB: 07/03/1984
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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210552 **Seq:** 1
Reported: 10/08/2005
Hospitalisation: Admitted to hospital
Onset Date: 08/01/2005
Outcome: Recovered

Gender: F
Weight: 78.00
Age: 20
DOB: 07/03/1984
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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 210553 **Seq:** 1
Reported: 10/08/2005
Hospitalisation: Admitted to hospital
Onset Date: 08/07/2004
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 48
DOB: 16/08/1955
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:

Report Details:

Case Number: 210555 **Seq:** 1
Reported: 10/08/2005
Hospitalisation:
Onset Date: 01/07/2005
Outcome: Not yet recovered

Gender: M
Weight: 90.00
Age: 23
DOB: 19/01/1982
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:

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:

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:

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
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:

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 Blood creatine phosphokinase incr Neuroleptic malignant syndrome Pyrexia		Patient experienced tachycardia 90-110, elevated creatinine kinase reported as 246, suspected neuroleptic malignant syndrome.	Clopine withheld.

Medicine Details:

LORAZEPAM (Other drug) **Reason:**
Tablet 6.0 Milligram Oral
Batch: **Started:** **Stopped:** 0

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

PARACETAMOL (Other drug) **Reason:**
Tablet 4.0 Gram Oral
Batch: **Started:** **Stopped:**

OLANZAPINE (Suspected) **Reason:**
Tablet 20.0 Milligram Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 211097 **Seq:** 1
Reported: 25/08/2005
Hospitalisation:
Onset Date: 08/08/2005
Outcome: Unknown

Gender: M
Weight: 0.00
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:

Report Details:

Case Number: 211537 **Seq:** 1
Reported: 09/09/2005
Hospitalisation: Required a visit to the doctor
Onset Date: 22/08/2005
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 43
DOB: 13/11/1961
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:

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:

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: **Age:** 36Y
Onset Date: 23/09/2005 **DOB:**
Outcome: Recovered **Causality:** Causality possible

Reaction Details:

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

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.

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 212584 **Seq:** 1
Reported: 14/10/2005
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 29
DOB: 22/07/1976
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 monitioring.

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:

Report Details:

Case Number: 212584 **Seq:** 1
Reported: 14/10/2005
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 29
DOB: 22/07/1976
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:

Report Details:

Case Number: 212584 **Seq:** 1
Reported: 14/10/2005
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2005
Outcome: Recovered

Gender: M
Weight: 0.00
Age: 29
DOB: 22/07/1976
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:

Report Details:

Case Number: 213135 **Seq:** 1 **Gender:** F
Reported: 07/11/2005 **Weight:** 39.00
Hospitalisation: **Age:** 34
Onset Date: 04/09/2005 **DOB:** 16/03/1971
Outcome: Recovered **Causality:** Causality possible

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.

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:

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 phosphokinase				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

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
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

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

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213447 **Seq:** 1
Reported: 15/11/2005
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Recovered

Gender: F
Weight: 0.00
Age: 20
DOB: 19/09/1985
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:

Report Details:

Case Number: 213524 **Seq:** 1
Reported: 17/11/2005
Hospitalisation:
Onset Date: 02/04/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 43
DOB: 23/08/1961
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome Blood creatine phosphokinase incr Hallucination, auditory Leukocytosis Pyrexia Suicidal ideation		The patient experienced suspected Neuroleptic Malignant Syndrome. She had increased temperatures, increased creatine kinase, was having disturbing thoughts, hearing voices and suicidal ideation.	Withheld neuroleptics initially, monitored temperature, BP, pulse, QID. Olanzapine restarted on 7/4/05.

Medicine Details:

Aripiprazole (Suspected) **Reason:**
Tablet 15.0 Milligram Daily Oral
Batch: **Started:** 17/03/2005 **Stopped:**

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details
17/11/2005	ALT = SGPT		02/04/2005	61	
17/11/2005	ALT = SGPT		04/04/2005	51	
17/11/2005	ALT = SGPT		11/04/2005	62	
17/11/2005	AST = SGOT		02/04/2005	36	
17/11/2005	AST = SGOT		04/04/2005	37	
17/11/2005	Creatinine		02/04/2005	0.11	
17/11/2005	Creatinine		11/04/2005	0.09	

Additional Information:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 213524 **Seq:** 1
Reported: 17/11/2005
Hospitalisation:
Onset Date: 02/04/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 43
DOB: 23/08/1961
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:

Report Details:

Case Number: 213524 **Seq:** 1
Reported: 17/11/2005
Hospitalisation:
Onset Date: 02/04/2005
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 43
DOB: 23/08/1961
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:

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:

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 Restlessness		The patient developed akathisia and inner restlessness, tongue and buccal movements, teeth chattering and vocal ties.	Changed to Seroquel 300mg bd.

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:

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 Resperidone.

Report Details:

Case Number: 214329 **Seq:** 1
Reported: 15/12/2005
Hospitalisation: Admitted to hospital
Onset Date: 27/11/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214329 **Seq:** 1
Reported: 15/12/2005
Hospitalisation: Admitted to hospital
Onset Date: 27/11/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
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:

Report Details:

Case Number: 214329 **Seq:** 1
Reported: 15/12/2005
Hospitalisation: Admitted to hospital
Onset Date: 27/11/2005
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
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:

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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 214549 **Seq:** 1
Reported: 04/01/2006
Hospitalisation:
Onset Date: 10/11/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 19
DOB: 13/05/1986
Causality: Causality possible

Reaction Details:

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

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:

Report Details:

Case Number: 214712 **Seq:** 1
Reported: 09/01/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99U
DOB:
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:

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 Drug exposure during pregnancy		Neonate has cardiac defect requiring surgery.	

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:

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 Blood creatine phosphokinase incr		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.	

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:

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:

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 MB				14/02/2006 CK - 282 15/02/2006 CK - 263

Additional Information:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 216020 **Seq:** 1
Reported: 20/02/2006
Hospitalisation:
Onset Date: 04/02/2006
Outcome: Not yet recovered

Gender: F
Weight: 70.00
Age: 29
DOB: 08/04/1976
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:

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 Oral
Batch: **Started:** **Stopped:** 0

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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:

Report Details:

Case Number: 216564 **Seq:** 1
Reported: 16/03/2006
Hospitalisation:
Onset Date: 15/04/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 25
DOB: 02/10/1979
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Dyskinesia Myoclonus		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.	

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 sereve side effects fromprevious antipsychotics, eg Quetiapine, Olanzapine and Risperidone.

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.

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 Erectile dysfunction		Patient developed marked sexual side effects, particularly impotence.	Ceased Abilify.

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.

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:

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.

Report Details:

Case Number: 218522 **Seq:** 1
Reported: 19/05/2006
Hospitalisation: Treated in outpatient department only.
Onset Date: 30/03/2006
Outcome: Recovered

Gender: M
Weight: 70.00
Age: 30
DOB: 13/09/1975
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.

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:

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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219054 **Seq:** 1
Reported: 07/06/2006
Hospitalisation:
Onset Date: 05/01/2006
Outcome: Not yet recovered

Gender: M
Weight: 92.30
Age: 43
DOB: 31/05/1962
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Psychotic disorder Hallucination Self mutilation		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.

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:

Report Details:

Case Number: 219223 **Seq:** 1
Reported: 19/06/2006
Hospitalisation: Admitted to hospital
Onset Date: 15/05/2006
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99u
DOB:
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 secreation of dntidiuretic hormone. About six weeks afte the start of therapy, the Aripipraxole 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.

Report Details:

Case Number: 219223 **Seq:** 1
Reported: 19/06/2006
Hospitalisation: Admitted to hospital
Onset Date: 15/05/2006
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99u
DOB:
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.

Report Details:

Case Number: 219223 **Seq:** 1
Reported: 19/06/2006
Hospitalisation: Admitted to hospital
Onset Date: 15/05/2006
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 99u
DOB:
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.

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219323 **Seq:** 1
Reported: 20/06/2006
Hospitalisation: Required a visit to the doctor
Onset Date: 13/04/2006
Outcome: Unknown

Gender: F
Weight: 69.00
Age: 58
DOB: 23/05/1947
Causality: Causality possible

Reaction Details:

Preferred Term	Severity	Report Description	Treatment
Low density lipoprotein increased		Rise in LDL level when swiched 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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 219616 **Seq:** 1 **Gender:** M
Reported: 03/07/2006 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: **DOB:** 22/12/1972
Outcome: Recovered **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:

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.

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 Ventricular dysfunction		Patient had shown a dilated left ventricle with mild to moderate left ventricular systolic dysfunction.	Abilify discontinued

Medicine Details:

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

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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

Report Details:

Case Number: 220455 **Seq:** 1
Reported: 31/07/2006
Hospitalisation: Admitted to hospital
Onset Date: 18/11/2004
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 19
DOB: 20/07/1985
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.

Report Details:

Case Number: 220457 **Seq:** 1
Reported: 31/07/2006
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 20
DOB: 20/07/1985
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 claves and wants to sit down. Excessive salivation, choreform 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.

Report Details:

Case Number: 220457 **Seq:** 1
Reported: 31/07/2006
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 20
DOB: 20/07/1985
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.

Report Details:

Case Number: 220457 **Seq:** 1
Reported: 31/07/2006
Hospitalisation: Admitted to hospital
Onset Date: 06/09/2005
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 20
DOB: 20/07/1985
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.

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:

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 Abdominal pain upper Chest pain		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.	

Medicine Details:

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

Laboratory Investigations:

Date	Type	Range	Date Tested	Result	Details

Additional Information:

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:

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 Akathisia Depression		Patient had feelings of despair, depression, akathisia.	

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:

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, howevere, 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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 224201 **Seq:** 1
Reported: 19/12/2006
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 70Y
DOB:
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.

Report Details:

Case Number: 224753 **Seq:** 1
Reported: 17/01/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 06/12/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 37
DOB: 20/08/1969
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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 224786 **Seq:** 1
Reported: 17/01/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 05/12/2006
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 37
DOB: 20/08/1969
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:

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:

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:

Report Details:

Case Number: 224834 **Seq:** 1
Reported: 18/01/2007
Hospitalisation: Admitted to hospital
Onset Date:
Outcome: Unknown

Gender: F
Weight: 0.00
Age: 18Y
DOB:
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.

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, swolen 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:

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:

Report Details:

Case Number: 225141 **Seq:** 1
Reported: 29/01/2007
Hospitalisation:
Onset Date: 10/11/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
Age: 62Y
DOB:
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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 225141 **Seq:** 1
Reported: 29/01/2007
Hospitalisation:
Onset Date: 10/11/2006
Outcome: Not yet recovered

Gender: M
Weight: 0.00
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:

Report Details:

Case Number: 225382 **Seq:** 1
Reported: 02/02/2007
Hospitalisation: Required a visit to the doctor
Onset Date: 04/01/2007
Outcome: Not yet recovered

Gender: M
Weight: 95.00
Age: 21
DOB: 18/11/1985
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.

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:

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:

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 Confusional state Hypersomnia		Urinary incontinence, sleep excessive, vagueness.	

Medicine Details:

DEXAMPHETAMINE SULPHATE (Other drug) **Reason:** Behavior disorders of childhod
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.

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:

Report Details:

Case Number: 226806 **Seq:** 1 **Gender:** F
Reported: 21/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 21Y
Onset Date: **DOB:**
Outcome: Unknown **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 aripirazole 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.

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 226926 **Seq:** 1 **Gender:** F
Reported: 23/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 05/12/2006 **DOB:** 03/07/1973
Outcome: Recovered **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 Fluoxamine 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.

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 226926 **Seq:** 1 **Gender:** F
Reported: 23/03/2007 **Weight:** 0.00
Hospitalisation: **Age:** 33
Onset Date: 05/12/2006 **DOB:** 03/07/1973
Outcome: Recovered **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.

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:

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 228346 **Seq:** 1
Reported: 09/05/2007
Hospitalisation: Admitted to hospital
Onset Date: 24/03/2007
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 46
DOB: 17/01/1961
Causality: Causality possible

Reaction Details:

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.

Unclear causality excluded GM medicines Only Tradenames: Abilify,Aripiprazole

Report Details:

Case Number: 228346 **Seq:** 1
Reported: 09/05/2007
Hospitalisation: Admitted to hospital
Onset Date: 24/03/2007
Outcome: Not yet recovered

Gender: F
Weight: 0.00
Age: 46
DOB: 17/01/1961
Causality: Causality possible

Reaction Details:

Medicine Details:

OLANZAPINE (Suspected) **Reason:**
7.5 Milligram Daily
Batch: **Started:** **Stopped:** 24/03/2007

Laboratory Investigations:

Additional Information:

History: Psychosis, depression, asthma and epilepsy.