

## clozapine to end January 2009

				Case Group	Death Outcomes	Sole	
Case Count				4362	282	3779	
Medicine	Reaction Count	Blood and lymphatic system disorders	Iron deficiency anaemia	1	0	1	
			Anaemia	36	2	33	
			Anaemia macrocytic	1	0	1	
			Anaemia neonatal	1	0	1	
			Hypochromic anaemia	1	0	1	
			Microcytic anaemia	2	0	2	
			Normochromic normocytic anaemia	1	0	0	
			Bone marrow failure	2	0	2	
			Pancytopenia	14	0	8	
			Coagulopathy	2	2	1	
			Disseminated intravascular coagulation	2	0	2	
			Haemolytic anaemia	1	0	1	
			Haemolysis	1	0	1	
			Thrombocythaemia	10	0	8	
			Thrombocytopenia	58	1	47	
			Anisocytosis	3	0	3	
			Microcytosis	1	0	1	
			Poikilocytosis	3	0	3	
			Rouleaux formation	2	0	2	
			Lymphadenopathy	4	0	3	
			Splenomegaly	6	1	4	
			Eosinophilia	161	0	144	
			Basophilia	1	0	1	
			Granulocytosis	3	0	3	
			Leukocytosis	136	5	121	
			Lymphocytosis	13	0	10	
			Monocytosis	3	0	3	
			Neutrophilia	28	0	23	
			Eosinopenia	4	0	4	
			Leukopenia	306	2	282	
			Lymphopenia	21	2	18	
			Monocytopenia	1	0	1	
			Agranulocytosis	130	3	112	
		Febrile neutropenia	1	0	1		
		Neutropenia	628	5	577		
		Blood and lymphatic system disorders			1588	23	1425
		Cardiac disorders					
		Atrioventricular block			3	0	3
		Atrioventricular block first degree			3	0	3
		Atrioventricular block second degree			1	0	1
		Bundle branch block			7	0	6
		Bundle branch block bilateral			1	0	0

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Medicine	Reaction Count	Cardiac disorders	Case Group	Death Outcomes	Sole
		Bundle branch block left	2	0	1
		Bundle branch block right	10	0	9
		Arrhythmia	21	5	15
		Bradycardia	12	0	12
		Extrasystoles	11	0	11
		Nodal arrhythmia	1	0	1
		Tachyarrhythmia	2	0	2
		Tachycardia	478	7	415
		Atrial fibrillation	29	2	25
		Atrial flutter	3	1	1
		Sinus bradycardia	1	0	1
		Sinus tachycardia	43	0	34
		Supraventricular extrasystoles	1	0	1
		Supraventricular tachycardia	8	0	4
		Cardiac arrest	25	18	15
		Cardio-respiratory arrest	3	3	3
		Ventricular extrasystoles	3	0	3
		Ventricular fibrillation	2	1	1
		Ventricular tachycardia	2	0	2
		Cardiac disorder	67	2	62
		Myopericarditis	2	0	2
		Cyanosis	8	2	4
		Palpitations	42	0	40
		Aortic valve disease	1	0	1
		Mitral valve disease	1	0	1
		Mitral valve incompetence	7	0	5
		Tricuspid valve incompetence	3	0	3
		Coronary artery occlusion	1	1	1
		Acute coronary syndrome	2	0	2
		Acute myocardial infarction	4	1	3
		Angina pectoris	7	0	7
		Myocardial infarction	39	22	34
		Myocardial ischaemia	13	3	13
		Cardiac failure	45	7	36
		Cardiac failure congestive	2	0	2
		Cardiogenic shock	1	0	1
		Ventricular failure	4	0	4
		Left ventricular failure	17	1	15
		Right ventricular failure	2	0	1
		Cardiomyopathy	193	6	172
		Congestive cardiomyopathy	5	0	5
		Hypertensive cardiomyopathy	1	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole
	<b>Cardiac disorders</b>	<b>Hypertrophic cardiomyopathy</b>	3	0	3
		<b>Atrial hypertrophy</b>	2	0	1
		<b>Cardiac hypertrophy</b>	1	0	1
		<b>Cardiomegaly</b>	36	3	28
		<b>Diastolic dysfunction</b>	3	0	3
		<b>Dilatation atrial</b>	8	0	8
		<b>Dilatation ventricular</b>	17	0	14
		<b>Left atrial dilatation</b>	4	0	3
		<b>Left ventricular dysfunction</b>	22	0	21
		<b>Left ventricular hypertrophy</b>	10	1	10
		<b>Right atrial dilatation</b>	1	0	1
		<b>Right ventricular hypertrophy</b>	1	0	1
		<b>Ventricular dysfunction</b>	14	0	11
		<b>Ventricular hyperkinesia</b>	2	0	2
		<b>Ventricular hypertrophy</b>	12	0	11
		<b>Ventricular hypokinesia</b>	9	0	8
		<b>Myocarditis</b>	317	14	288
		<b>Pericarditis</b>	35	1	31
		<b>Cardiac tamponade</b>	3	0	3
		<b>Pericardial effusion</b>	29	1	25
	<b>Cardiac disorders</b>	<b>1668</b>	<b>102</b>	<b>1457</b>	
	<b>Congenital, familial and genetic disorders</b>	<b>Deafness congenital</b>	1	0	1
		<b>Cleft palate</b>	1	0	0
		<b>Congenital foot malformation</b>	1	0	0
		<b>Congenital, familial and genetic disorders</b>	3	0	1
	<b>Ear and labyrinth disorders</b>	<b>Deafness</b>	1	0	1
		<b>Vertigo</b>	1	0	1
		<b>Ear and labyrinth disorders</b>	2	0	2
	<b>Endocrine disorders</b>	<b>Hyperadrenocorticism</b>	1	0	1
		<b>Addison's disease</b>	1	0	1
		<b>Hyperprolactinaemia</b>	2	0	1
		<b>Diabetes insipidus</b>	1	0	1
		<b>Inappropriate antidiuretic hormone secretion</b>	1	0	0
		<b>Hyperparathyroidism</b>	1	0	1
		<b>Hypoparathyroidism</b>	2	0	2
		<b>Thyroiditis</b>	1	0	1
		<b>Hypothyroidism</b>	1	0	1
	<b>Endocrine disorders</b>	<b>11</b>	<b>0</b>	<b>9</b>	
	<b>Eye disorders</b>	<b>Cataract</b>	3	0	2
		<b>Eye disorder</b>	1	0	1
		<b>Retinal disorder</b>	1	0	0

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Eye disorders</b>	<b>Glaucoma</b>	1	0	0
			<b>Conjunctivitis</b>	1	0	1
			<b>Blepharospasm</b>	1	0	1
			<b>Eyelid ptosis</b>	1	0	1
			<b>Oculogyric crisis</b>	3	0	3
			<b>Miosis</b>	1	0	1
			<b>Mydriasis</b>	1	0	1
			<b>Pupillary reflex impaired</b>	1	0	0
			<b>Photophobia</b>	1	0	1
			<b>Retinal detachment</b>	1	0	1
			<b>Night blindness</b>	1	0	1
			<b>Diplopia</b>	1	0	1
			<b>Vision blurred</b>	3	0	3
			<b>Visual impairment</b>	6	0	6
			<b>Optic neuropathy</b>	1	0	0
			<b>Eye disorders</b>	29	0	24
		<b>Gastrointestinal disorders</b>	<b>Hiatus hernia</b>	1	0	1
			<b>Anorectal disorder</b>	1	0	1
			<b>Pancreatitis</b>	13	0	8
			<b>Pancreatitis acute</b>	3	0	1
			<b>Gastrointestinal disorder</b>	5	1	4
			<b>Oesophageal varices haemorrhage</b>	1	0	1
			<b>Rectal haemorrhage</b>	2	0	2
			<b>Gastrointestinal haemorrhage</b>	3	2	3
			<b>Haematemesis</b>	7	0	7
			<b>Melaena</b>	2	0	2
			<b>Colitis</b>	7	0	6
			<b>Colitis ulcerative</b>	1	0	0
			<b>Gastritis</b>	3	0	3
			<b>Crohn's disease</b>	1	0	1
			<b>Duodenitis</b>	1	0	1
			<b>Enteritis</b>	2	0	2
			<b>Inflammatory bowel disease</b>	1	0	1
			<b>Oesophagitis</b>	5	0	5
			<b>Reflux oesophagitis</b>	2	0	2
			<b>Proctitis</b>	1	0	1
			<b>Diarrhoea</b>	77	0	67
			<b>Constipation</b>	66	6	56
			<b>Gastrooesophageal reflux disease</b>	8	0	8
			<b>Intestinal dilatation</b>	1	0	1
			<b>Ileus paralytic</b>	8	1	5
			<b>Megacolon</b>	1	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Gastrointestinal disorders</b>	<b>Gastrointestinal sounds abnormal</b>	1	0	1
			Dyspepsia	15	1	14
			Faecaloma	3	0	3
			Abdominal distension	8	0	7
			Flatulence	2	1	2
			Abdominal pain	45	2	34
			Abdominal pain upper	7	0	6
			Abdominal rigidity	1	0	1
			Abdominal discomfort	2	0	2
			Dysphagia	23	0	21
			Faecal incontinence	5	0	4
			Nausea	122	2	103
			Vomiting	149	8	119
			Small intestinal obstruction	2	0	2
			Ileus	2	1	2
			Intestinal obstruction	26	4	25
			Intestinal perforation	6	3	5
			Large intestine perforation	2	0	2
			Oesophagitis ulcerative	3	0	3
			Peptic ulcer	2	0	2
			Gastrointestinal necrosis	3	2	2
			Intestinal ischaemia	1	1	1
			Varices oesophageal	1	0	1
			Coeliac disease	1	0	0
			Odynophagia	1	0	1
			Mouth ulceration	3	0	3
			Peritonitis	4	1	4
			Salivary hypersecretion	124	1	108
			Parotid gland enlargement	1	0	1
			Salivary gland enlargement	16	0	12
			Swollen tongue	1	0	1
			Tongue oedema	4	0	2
			<b>Gastrointestinal disorders</b>	<b>809</b>	<b>37</b>	<b>684</b>
		<b>General disorders and administration site conditions</b>	<b>Hyperthermia</b>	1	0	1
			Hyperthermia malignant	1	0	1
			Hypothermia	4	0	3
			Hyperpyrexia	4	0	4
			Pyrexia	453	9	389
			Death	74	67	60
			Sudden death	116	115	92
			Asthenia	30	0	26
			Fatigue	74	2	69

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Medicine	Reaction Count	General disorders and administration site conditions		Case Group	Death Outcomes	Sole
			Malaise	110	3	97
			Sluggishness	1	0	1
			Abasia	1	0	1
			Gait disturbance	12	2	9
			Condition aggravated	5	0	5
			Crepitations	1	1	1
			Disease progression	1	0	1
			Exercise tolerance decreased	1	0	1
			Foaming at mouth	1	0	0
			General physical health deterioration	1	0	1
			Influenza like illness	69	4	64
			Irritability	2	0	1
			Multi-organ failure	2	1	1
			Swelling	1	0	1
			Mucosal inflammation	1	0	1
			Face oedema	5	0	5
			Generalised oedema	1	1	1
			Gravitational oedema	5	1	4
			Oedema	3	0	2
			Oedema peripheral	18	0	15
			Pitting oedema	1	0	1
			Chest pain	176	2	157
			Pain	17	0	16
			Chest discomfort	13	1	10
			Chills	17	0	15
			Feeling abnormal	4	0	4
			Feeling cold	1	0	1
			Feeling hot	1	0	1
			Feeling of body temperature change	4	0	4
			Hunger	1	0	1
			Thirst	3	0	3
			Drug interaction	14	0	0
			Drug effect decreased	1	0	1
			Drug ineffective	65	2	58
			Drug tolerance	1	0	1
			Therapeutic response decreased	13	0	9
			Therapeutic response increased	1	0	0
			Therapeutic response unexpected with drug substitution	2	0	2
			Drug withdrawal syndrome	6	0	5
			Rebound effect	1	0	0
			<b>General disorders and administration site conditions</b>	<b>1340</b>	<b>211</b>	<b>1146</b>

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Hepatobiliary disorders</b>	Cholangitis	1	0	1
			Cholecystitis	1	0	1
			Cholelithiasis	2	0	2
			Gallbladder disorder	1	0	1
			Cholestasis	3	0	2
			Hepatitis cholestatic	3	0	3
			Hyperbilirubinaemia	1	0	0
			Jaundice	5	1	4
			Jaundice cholestatic	1	0	1
			Hepatic function abnormal	91	1	73
			Hepatic failure	1	1	1
			Hepatic cirrhosis	1	1	0
			Hepatomegaly	7	0	3
			Hepatosplenomegaly	2	0	1
			Hepatosplenomegaly neonatal	1	0	0
			Hepatic necrosis	1	0	1
			Hepatic steatosis	9	0	5
			Hepatitis	20	1	18
			<b>Hepatobiliary disorders</b>	<b>151</b>	<b>5</b>	<b>117</b>
			<b>Immune system disorders</b>	Hypersensitivity	3	0
		Drug hypersensitivity		1	0	1
		Immune system disorders		4	0	4
		<b>Infections and infestations</b>	Bacterial infection	6	0	6
			Cellulitis	4	0	3
			Clostridial infection	1	0	1
			Haemophilus infection	1	0	1
			Helicobacter infection	5	0	5
			Lung infection pseudomonal	1	0	1
			Streptococcal infection	1	0	1
			Streptococcal sepsis	2	1	2
			Tertiary syphilis	1	0	1
			Candidiasis	2	0	2
			Anal abscess	1	0	1
			Appendicitis	3	1	3
			Gastroenteritis	9	2	7
			Endocarditis	3	0	3
			Meningitis	2	1	2
			Parotitis	1	0	1
			Tooth abscess	2	0	2
			Otitis media	1	0	1
			Hepatic infection	1	0	1
			Abscess	1	0	1

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Infections and infestations</b>	<b>Infection</b>	<b>19</b>	<b>1</b>	<b>17</b>
			Infection parasitic	1	0	1
			Infection susceptibility increased	1	0	1
			Postoperative wound infection	1	0	1
			Respiratory tract infection	3	0	3
			Bronchiectasis	2	0	2
			Bronchitis	6	1	5
			Bronchopneumonia	3	3	3
			Lower respiratory tract infection	11	0	11
			Lung infection	1	1	1
			Pneumonia	109	16	96
			Pneumonia primary atypical	3	0	2
			Pyothorax	1	0	1
			Necrotising fasciitis	1	0	1
			Sepsis	22	7	16
			Rash pustular	5	0	5
			Subcutaneous abscess	1	1	1
			Nasopharyngitis	3	0	1
			Pharyngitis	31	0	27
			Pharyngolaryngeal abscess	1	0	1
			Rhinitis	4	0	4
			Sinusitis	2	0	2
			Upper respiratory tract infection	12	1	11
			Pyelonephritis	2	0	1
			Urinary tract infection	9	1	8
			Mycoplasma infection	1	0	1
			Pneumonia mycoplasmal	1	0	1
			Cytomegalovirus infection	1	0	1
			Infectious mononucleosis	1	0	1
			Hepatitis C	1	0	1
			Herpes zoster	3	0	2
			Varicella	3	0	2
			Influenza	7	0	6
			Measles	1	0	1
			Hepatitis viral	1	0	0
			Respiratory tract infection viral	1	1	1
			Viral infection	17	0	17
			<b>Infections and infestations</b>	<b>340</b>	<b>38</b>	<b>301</b>
		<b>Injury, poisoning and procedural complications</b>	<b>Drug toxicity</b>	<b>6</b>	<b>0</b>	<b>3</b>
			Therapeutic agent toxicity	3	0	1
			Drug exposure during pregnancy	2	0	2
			Subdural haematoma	1	0	0



## clozapine to end January 2009

			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Injury, poisoning and procedural complications	Fall	12	2	9
			Heat stroke	1	1	0
			Incorrect dose administered	2	0	2
			Wrong drug administered	1	0	1
			Drug prescribing error	1	0	1
			Medication error	5	0	4
			Accidental exposure	2	0	2
			Accidental overdose	7	1	6
			Intentional overdose	10	2	8
			Overdose	15	0	13
			Cardiac function disturbance postoperative	2	0	2
			Injury, poisoning and procedural complications	70	6	54
		Investigations	Cardiac murmur	2	0	2
			Cardiac output decreased	1	0	1
			Echocardiogram abnormal	57	0	57
			Ejection fraction abnormal	2	0	2
			Ejection fraction decreased	65	1	58
			Cardiac function test abnormal	1	0	1
			Scan myocardial perfusion abnormal	1	0	1
			ECG signs of ventricular hypertrophy	1	0	1
			Electrocardiogram P wave biphasic	1	0	1
			Electrocardiogram QT prolonged	27	0	17
			Electrocardiogram QT shortened	1	0	1
			Electrocardiogram ST segment abnormal	2	0	2
			Electrocardiogram ST segment depression	2	0	1
			Electrocardiogram ST segment elevation	5	0	5
			Electrocardiogram ST-T change	2	0	2
			Electrocardiogram ST-T segment abnormal	1	0	1
			Electrocardiogram T wave abnormal	6	0	6
			Electrocardiogram T wave amplitude decreased	2	0	2
			Electrocardiogram T wave inversion	26	0	22
			Electrocardiogram abnormal	130	1	119
			Electrocardiogram change	2	0	2
Electrocardiogram repolarisation abnormality	1	0	1			
Exercise electrocardiogram abnormal	1	0	1			
QRS axis abnormal	2	0	1			
ECG signs of myocardial ischaemia	1	0	1			

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole
		Heart rate increased	19	0	17
		Heart rate irregular	5	0	4
		Pulse abnormal	1	0	1
		Blood pressure decreased	6	0	5
		Blood pressure diastolic increased	2	0	2
		Blood pressure increased	15	0	13
		Blood pressure orthostatic decreased	1	0	1
		Blood insulin abnormal	1	0	1
		Blood prolactin increased	4	0	3
		Blood thyroid stimulating hormone decreased	1	0	1
		Thyroid function test abnormal	1	0	1
		Blood creatine phosphokinase MB increased	3	0	3
		Blood creatine phosphokinase increased	205	5	175
		Cardiac enzymes increased	9	0	8
		Troponin I increased	34	0	31
		Troponin T increased	5	0	4
		Troponin increased	131	1	123
		Blood alkaline phosphatase increased	8	0	5
		Blood lactate dehydrogenase increased	4	0	3
		Blood amylase increased	5	0	2
		Lipase increased	5	0	2
		International normalised ratio increased	1	0	1
		Prothrombin level decreased	1	0	1
		Prothrombin time prolonged	1	0	0
		Red blood cell sedimentation rate abnormal	1	0	1
		Red blood cell sedimentation rate increased	39	1	27
		Platelet count decreased	14	0	10
		Platelet count increased	8	0	6
		Haematocrit decreased	4	0	4
		Haemoglobin decreased	11	1	9
		Mean cell volume decreased	2	0	2
		Red blood cell count decreased	3	0	3
		Red blood cell count increased	2	0	1
		Red blood cell elliptocytes present	1	0	1
		Red cell distribution width increased	2	0	1
		Band neutrophil percentage increased	1	0	1
		Eosinophil count decreased	1	0	1
		Eosinophil count increased	33	1	29
		Lymphocyte count decreased	10	0	8

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole
		Lymphocyte count increased	1	0	1
		Lymphocyte morphology abnormal	2	0	2
		Monocyte count decreased	1	0	1
		Monocyte count increased	6	0	6
		Neutrophil count decreased	45	0	42
		Neutrophil count increased	48	0	43
		Neutrophil morphology abnormal	1	0	1
		Neutrophil toxic granulation present	1	0	1
		White blood cell count decreased	54	0	51
		White blood cell count increased	60	1	50
		Ultrasound liver abnormal	1	0	0
		Alanine aminotransferase increased	13	0	9
		Ammonia increased	1	0	0
		Aspartate aminotransferase increased	13	0	9
		Blood bilirubin abnormal	1	0	1
		Blood bilirubin increased	2	0	2
		Gamma-glutamyltransferase increased	15	0	13
		Hepatic enzyme abnormal	1	0	0
		Hepatic enzyme increased	8	0	7
		Liver function test abnormal	38	0	30
		Transaminases increased	2	0	1
		Antinuclear antibody positive	1	0	1
		Echography abnormal	1	0	1
		Blood test abnormal	1	0	1
		Blood cholesterol increased	13	1	12
		High density lipoprotein decreased	3	0	3
		Low density lipoprotein increased	1	0	1
		Lipids abnormal	1	0	0
		Lipids increased	1	0	1
		Blood triglycerides increased	14	0	13
		Blood lactic acid increased	1	0	1
		Oxygen saturation decreased	5	0	2
		Blood glucose increased	27	1	21
		Glucose tolerance test abnormal	1	0	1
		Blood homocysteine increased	1	0	1
		Blood uric acid increased	2	0	2
		Myoglobin blood increased	1	0	1
		Myoglobin urine present	1	0	1
		Electroencephalogram abnormal	8	0	6
		Glasgow coma scale abnormal	1	0	0
		Body mass index increased	1	0	0
		Body temperature increased	20	0	17

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole
		Respiratory rate increased	1	0	0
		Weight decreased	18	0	17
		Weight increased	110	2	93
		Blood albumin decreased	1	0	1
		Blood albumin increased	1	0	1
		C-reactive protein increased	67	0	57
		Globulins increased	1	0	1
		Protein total increased	2	0	2
		Blood creatine increased	3	0	3
		Blood creatinine decreased	1	0	1
		Blood creatinine increased	6	0	5
		Blood urea decreased	1	0	1
		Blood urea increased	2	0	1
		Blood urea nitrogen/creatinine ratio decreased	1	0	1
		Creatinine urine increased	1	0	0
		Antipsychotic drug level below therapeutic	1	0	1
		Antipsychotic drug level increased	8	1	4
		Drug level above therapeutic	11	0	6
		Drug level below therapeutic	3	0	3
		Drug level changed	4	0	4
		Drug level decreased	26	0	20
		Drug level fluctuating	2	0	0
		Drug level increased	91	5	53
		Blood calcium decreased	2	0	1
		Blood phosphorus decreased	2	0	2
		Blood potassium	1	0	1
		Blood potassium abnormal	1	0	1
		Blood sodium abnormal	1	0	1
		Blood sodium decreased	1	0	1
		Blood osmolarity decreased	2	0	2
		Blood osmolarity increased	1	0	1
		Urine osmolarity decreased	1	0	1
		<b>Investigations</b>	<b>1735</b>	<b>22</b>	<b>1461</b>
		<b>Metabolism and nutrition disorders</b>			
		Ketoacidosis	1	0	1
		Ketosis	11	2	11
		Metabolic acidosis	1	0	0
		Acidosis	3	2	2
		Anorexia	24	2	18
		Decreased appetite	1	0	1
		Increased appetite	3	0	3
		Central obesity	1	0	1

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Metabolism and nutrition disorders</b>	<b>Obesity</b>	4	2	4
			<b>Hypercalcaemia</b>	4	0	3
			<b>Hypocalcaemia</b>	4	1	2
			<b>Hyperphosphataemia</b>	2	0	2
			<b>Hypophosphataemia</b>	1	0	1
			<b>Diabetic ketoacidosis</b>	6	0	5
			<b>Hyperglycaemic hyperosmolar nonketotic syndrome</b>	1	0	1
			<b>Hypochloraemia</b>	1	0	1
			<b>Electrolyte imbalance</b>	2	1	2
			<b>Polydipsia</b>	17	0	13
			<b>Hyperkalaemia</b>	2	2	0
			<b>Hypokalaemia</b>	8	1	6
			<b>Hypernatraemia</b>	2	0	2
			<b>Hyponatraemia</b>	22	4	15
			<b>Dehydration</b>	16	0	13
			<b>Diabetes mellitus</b>	94	2	85
			<b>Diabetes mellitus inadequate control</b>	2	0	1
			<b>Type 1 diabetes mellitus</b>	6	1	6
			<b>Type 2 diabetes mellitus</b>	9	1	8
			<b>Glucose tolerance impaired</b>	5	0	4
			<b>Hyperglycaemia</b>	64	1	61
			<b>Insulin resistance</b>	2	0	1
			<b>Hypoglycaemia</b>	3	1	3
			<b>Hypercholesterolaemia</b>	3	0	3
			<b>Hypertriglyceridaemia</b>	2	0	2
			<b>Hyperlipidaemia</b>	7	1	6
			<b>Dyslipidaemia</b>	1	0	1
			<b>Metabolic syndrome</b>	2	0	2
			<b>Hyperammonaemia</b>	1	0	0
			<b>Hypoproteinaemia</b>	1	0	1
			<b>Hyperuricaemia</b>	1	0	1
			<b>Vitamin B12 deficiency</b>	1	0	1
			<b>Metabolism and nutrition disorders</b>	<b>341</b>	<b>24</b>	<b>293</b>
		<b>Musculoskeletal and connective tissue disorders</b>	<b>Pathological fracture</b>	1	0	1
			<b>Arthralgia</b>	14	0	12
			<b>Joint stiffness</b>	2	0	1
			<b>Myositis</b>	4	0	4
			<b>Myalgia</b>	29	0	24
			<b>Muscle atrophy</b>	1	0	1
			<b>Muscle disorder</b>	1	0	1
			<b>Muscle spasms</b>	4	0	4
			<b>Muscle twitching</b>	8	0	7

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole
	<b>Musculoskeletal and connective tissue disorders</b>	<b>Muscle rigidity</b>	4	0	2
		<b>Torticollis</b>	1	0	1
		<b>Trismus</b>	1	0	1
		<b>Muscular weakness</b>	3	0	2
		<b>Myopathy</b>	6	0	6
		<b>Rhabdomyolysis</b>	8	1	6
		<b>Mobility decreased</b>	2	0	2
		<b>Musculoskeletal stiffness</b>	3	0	2
		<b>Posture abnormal</b>	2	0	2
		<b>Neck mass</b>	1	0	1
		<b>Back pain</b>	2	0	1
		<b>Musculoskeletal chest pain</b>	1	0	1
		<b>Pain in extremity</b>	1	0	1
		<b>Tendonitis</b>	1	0	1
		<b>Musculoskeletal and connective tissue disorders</b>	<b>100</b>	<b>1</b>	<b>84</b>
		<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>Breast cancer</b>	1	0
	<b>Breast cancer female</b>		3	1	1
	<b>Pituitary tumour benign</b>		1	0	1
	<b>Adrenal carcinoma</b>		1	0	1
	<b>Pituitary tumour</b>		1	0	0
	<b>Pseudolymphoma</b>		4	1	3
	<b>Hepatic neoplasm malignant</b>		2	0	2
	<b>Leukaemia</b>		4	2	3
	<b>Chronic lymphocytic leukaemia</b>		1	0	1
	<b>Lymphocytic leukaemia</b>		1	0	1
	<b>Lymphoma</b>		5	0	3
	<b>Angiocentric lymphoma</b>		1	1	0
	<b>Metastatic neoplasm</b>		1	1	1
	<b>Neoplasm malignant</b>		2	2	2
	<b>Brain neoplasm malignant</b>		2	2	2
	<b>Multiple myeloma</b>		3	0	2
	<b>Bladder cancer</b>		1	0	1
	<b>Testis cancer</b>		1	0	1
	<b>Lung neoplasm malignant</b>		1	0	1
	<b>Malignant melanoma</b>		1	0	1
	<b>Basal cell carcinoma</b>	1	0	1	
	<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>38</b>	<b>10</b>	<b>29</b>	
<b>Nervous system disorders</b>	<b>Cerebral haemorrhage</b>	1	0	1	
	<b>Cerebral haemorrhage neonatal</b>	1	0	0	
	<b>Cerebral infarction</b>	2	1	2	
	<b>Cerebrovascular accident</b>	6	4	4	

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Nervous system disorders</b>	<b>Haemorrhage intracranial</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Cerebrovascular disorder</b>	<b>7</b>	<b>3</b>	<b>6</b>
			<b>Transient ischaemic attack</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Cranial nerve disorder</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Facial palsy</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Facial spasm</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Encephalopathy</b>	<b>3</b>	<b>0</b>	<b>3</b>
			<b>Toxic encephalopathy</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Headache</b>	<b>50</b>	<b>2</b>	<b>41</b>
			<b>Migraine</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Dementia</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Amnesia</b>	<b>3</b>	<b>0</b>	<b>2</b>
			<b>Memory impairment</b>	<b>4</b>	<b>0</b>	<b>3</b>
			<b>Cognitive disorder</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Disturbance in attention</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Mental impairment</b>	<b>5</b>	<b>0</b>	<b>4</b>
			<b>Choreoathetosis</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Akathisia</b>	<b>5</b>	<b>0</b>	<b>3</b>
			<b>Dyskinesia</b>	<b>11</b>	<b>0</b>	<b>7</b>
			<b>Extrapyramidal disorder</b>	<b>9</b>	<b>0</b>	<b>4</b>
			<b>Hyperkinesia</b>	<b>3</b>	<b>0</b>	<b>2</b>
			<b>Hypokinesia</b>	<b>7</b>	<b>0</b>	<b>6</b>
			<b>Movement disorder</b>	<b>3</b>	<b>0</b>	<b>3</b>
			<b>Tardive dyskinesia</b>	<b>12</b>	<b>0</b>	<b>4</b>
			<b>Dystonia</b>	<b>21</b>	<b>0</b>	<b>14</b>
			<b>Opisthotonus</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Hemiparesis</b>	<b>3</b>	<b>1</b>	<b>1</b>
			<b>Hemiplegia</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Paresis</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Cogwheel rigidity</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Parkinson's disease</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Parkinsonian gait</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Parkinsonism</b>	<b>4</b>	<b>0</b>	<b>2</b>
			<b>Tremor</b>	<b>35</b>	<b>0</b>	<b>29</b>
			<b>Hyperreflexia</b>	<b>2</b>	<b>0</b>	<b>0</b>
			<b>Hyporeflexia</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Reflexes abnormal</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Ataxia</b>	<b>13</b>	<b>0</b>	<b>9</b>
			<b>Balance disorder</b>	<b>5</b>	<b>0</b>	<b>5</b>
			<b>Coordination abnormal</b>	<b>12</b>	<b>0</b>	<b>11</b>
			<b>Dysstasia</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Nystagmus</b>	<b>1</b>	<b>0</b>	<b>1</b>

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Nervous system disorders</b>	<b>Coma</b>	<b>20</b>	<b>5</b>	<b>12</b>
			<b>Aphasia</b>	<b>5</b>	<b>0</b>	<b>4</b>
			<b>Altered state of consciousness</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Consciousness fluctuating</b>	<b>9</b>	<b>0</b>	<b>7</b>
			<b>Depressed level of consciousness</b>	<b>10</b>	<b>2</b>	<b>5</b>
			<b>Lethargy</b>	<b>22</b>	<b>0</b>	<b>20</b>
			<b>Loss of consciousness</b>	<b>18</b>	<b>1</b>	<b>15</b>
			<b>Sedation</b>	<b>46</b>	<b>1</b>	<b>37</b>
			<b>Somnolence</b>	<b>112</b>	<b>3</b>	<b>90</b>
			<b>Stupor</b>	<b>3</b>	<b>0</b>	<b>1</b>
			<b>Syncope</b>	<b>73</b>	<b>8</b>	<b>54</b>
			<b>Dizziness</b>	<b>94</b>	<b>2</b>	<b>87</b>
			<b>Dizziness postural</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b> Drooling</b>	<b>8</b>	<b>0</b>	<b>8</b>
			<b>Meningism</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Myoclonus</b>	<b>18</b>	<b>0</b>	<b>11</b>
			<b>Tongue biting</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Unresponsive to stimuli</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Crying</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Paraesthesia</b>	<b>7</b>	<b>0</b>	<b>6</b>
			<b>Aura</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Dysgeusia</b>	<b>3</b>	<b>0</b>	<b>3</b>
			<b>Hypoaesthesia</b>	<b>5</b>	<b>0</b>	<b>4</b>
			<b>Restless legs syndrome</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Sensory disturbance</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Dysarthria</b>	<b>22</b>	<b>1</b>	<b>17</b>
			<b>Incoherent</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Speech disorder</b>	<b>15</b>	<b>0</b>	<b>14</b>
			<b>Visual field defect</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Anticholinergic syndrome</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Cholinergic syndrome</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Upper motor neurone lesion</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Hypertonia</b>	<b>15</b>	<b>0</b>	<b>10</b>
			<b>Hypotonia</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Neuroleptic malignant syndrome</b>	<b>99</b>	<b>3</b>	<b>66</b>
			<b>Serotonin syndrome</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Muscle contractions involuntary</b>	<b>3</b>	<b>0</b>	<b>3</b>
			<b>Neuropathy peripheral</b>	<b>2</b>	<b>0</b>	<b>2</b>
			<b>Petit mal epilepsy</b>	<b>1</b>	<b>0</b>	<b>1</b>
			<b>Grand mal convulsion</b>	<b>58</b>	<b>0</b>	<b>37</b>
			<b>Complex partial seizures</b>	<b>1</b>	<b>0</b>	<b>0</b>
			<b>Convulsion</b>	<b>236</b>	<b>9</b>	<b>182</b>



## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Nervous system disorders</b>	<b>Epilepsy</b>	5	0	4
			Myoclonic epilepsy	1	0	1
			Partial seizures	1	0	1
			Circadian rhythm sleep disorder	1	0	1
			Cataplexy	1	0	1
			Hypersomnia	1	0	1
			Cerebral atrophy	1	0	0
			<b>Nervous system disorders</b>	<b>1189</b>	<b>46</b>	<b>909</b>
		<b>Pregnancy, puerperium and perinatal conditions</b>	<b>Abortion spontaneous</b>	2	0	2
			Intra-uterine death	1	0	1
			Foetal distress syndrome	2	0	1
			Weight decrease neonatal	1	0	0
			<b>Pregnancy, puerperium and perinatal conditions</b>	<b>6</b>	<b>0</b>	<b>4</b>
		<b>Psychiatric disorders</b>	<b>Agitation</b>	24	1	14
			<b>Anxiety</b>	22	1	18
			<b>Stress</b>	1	1	0
			<b>Tension</b>	1	0	0
			<b>Panic attack</b>	2	1	1
			<b>Neurosis</b>	15	0	14
			<b>Obsessive-compulsive disorder</b>	7	0	5
			<b>Catatonia</b>	6	0	4
			<b>Restlessness</b>	4	0	4
			<b>Dysphemia</b>	1	0	1
			<b>Confusional state</b>	77	2	62
			<b>Disorientation</b>	4	1	2
			<b>Delirium</b>	38	2	26
			<b>Depression</b>	10	2	6
			<b>Depressed mood</b>	1	0	1
			<b>Depersonalisation</b>	2	0	2
			<b>Delusion</b>	7	0	4
			<b>Hallucination</b>	13	1	11
			<b>Hallucination, auditory</b>	7	0	5
			<b>Hallucination, visual</b>	2	0	2
			<b>Illusion</b>	1	0	1
			<b>Thinking abnormal</b>	6	1	5
			<b>Impulsive behaviour</b>	1	0	0
			<b>Mania</b>	4	0	4
			<b>Affect lability</b>	1	0	1
		<b>Inappropriate affect</b>	1	0	1	
		<b>Elevated mood</b>	1	0	1	
		<b>Emotional distress</b>	2	0	2	
		<b>Mood swings</b>	1	0	0	

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Psychiatric disorders</b>	Apathy	4	0	4
			Aggression	8	0	7
			Disturbance in social behaviour	1	0	1
			Paranoia	6	1	3
			Social avoidant behaviour	1	0	1
			Violence-related symptom	1	0	0
			Abnormal behaviour	7	1	2
			Mental disorder	6	0	6
			Mental status changes	1	0	1
			Alcohol withdrawal syndrome	1	0	1
			Withdrawal syndrome	29	1	22
			Delusional disorder, mixed type	1	0	1
			Acute psychosis	1	0	1
			Psychotic disorder	43	0	32
			Schizophreniform disorder	2	0	2
			Schizophrenia	3	0	3
			Libido increased	1	0	1
			Insomnia	4	1	4
			Nightmare	1	0	1
			Somnambulism	1	0	1
			Sleep disorder	2	0	2
			Polydipsia psychogenic	1	0	0
			Completed suicide	11	11	9
			Suicidal ideation	2	0	1
			Suicide attempt	55	18	50
		<b>Psychiatric disorders</b>	<b>455</b>	<b>46</b>	<b>353</b>	
		<b>Renal and urinary disorders</b>	Nephritis	1	0	0
			Tubulointerstitial nephritis	6	0	6
			Renal disorder	1	1	1
			Oliguria	1	0	1
			Renal failure	7	0	6
			Renal failure acute	22	3	16
			Renal impairment	21	1	17
			Hydronephrosis	2	0	2
			Ureteric obstruction	1	0	1
Dysuria	4		0	3		
Enuresis	8		0	7		
Incontinence	1		0	1		
Pollakiuria	5		0	5		
Urinary incontinence	63		0	53		
Urinary retention	6		0	5		
Albuminuria	2	1	0			

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Renal and urinary disorders</b>	Glycosuria	2	0	2
			Haematuria	2	1	0
			Myoglobinuria	3	0	2
			Nocturia	4	0	4
			Polyuria	12	0	10
			Nephrolithiasis	1	0	1
			<b>Renal and urinary disorders</b>	<b>175</b>	<b>7</b>	<b>143</b>
		<b>Reproductive system and breast disorders</b>	Gynaecomastia	1	0	1
			Breast tenderness	1	0	1
			Galactorrhoea	3	0	1
			Dysmenorrhoea	1	0	0
			Amenorrhoea	2	0	1
			Oligomenorrhoea	1	0	0
			Menorrhagia	1	0	0
			Ovarian cyst	2	0	2
			Polycystic ovaries	1	0	1
			Penis disorder	1	0	1
			Benign prostatic hyperplasia	1	0	1
			Prostatism	1	0	1
			Ejaculation disorder	2	0	2
			Ejaculation failure	17	0	13
			Erectile dysfunction	6	0	5
			Priapism	6	0	6
			Retrograde ejaculation	1	0	1
			Sexual dysfunction	3	0	3
			Testicular disorder	2	0	2
			<b>Reproductive system and breast disorders</b>	<b>53</b>	<b>0</b>	<b>42</b>
		<b>Respiratory, thoracic and mediastinal disorders</b>	Asthma	6	2	6
			Bronchospasm	14	1	13
			Chronic obstructive pulmonary disease	1	1	1
			Obstructive airways disorder	1	0	1
			Wheezing	5	0	4
			Alveolitis	1	0	1
			Alveolitis allergic	3	0	2
			Eosinophilic pneumonia	1	0	1
			Pneumonia aspiration	5	2	5
Pneumonitis	2		0	2		
Interstitial lung disease	1		0	1		
Lung consolidation	1		0	1		
Lung infiltration	2		0	2		
Pulmonary fibrosis	2		0	2		
<b>Pulmonary oedema</b>	<b>13</b>		<b>5</b>	<b>9</b>		

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole		
		Respiratory, thoracic and mediastinal disorders	Infantile apnoeic attack	1	0	0	
			Pleurisy	2	0	1	
			Pleural effusion	15	0	13	
			Pulmonary hypertension	2	0	1	
			Pulmonary embolism	24	7	18	
			Apnoea	6	1	6	
			Dyspnoea	155	6	129	
			Dyspnoea exertional	2	0	2	
			Hyperventilation	5	0	2	
			Hypoventilation	2	0	2	
			Orthopnoea	2	0	2	
			Respiratory arrest	2	1	2	
			Respiratory depression	7	1	5	
			Respiratory distress	1	0	0	
			Sleep apnoea syndrome	2	0	2	
			Tachypnoea	1	0	1	
			Asphyxia	4	4	4	
			Hypoxia	17	2	10	
			Cough	32	1	27	
			Haemoptysis	1	0	1	
			Productive cough	7	0	6	
			Hiccups	1	0	1	
			Pleuritic pain	13	0	10	
			Respiratory failure	9	7	8	
			Aspiration	5	4	5	
			Respiratory disorder	11	1	8	
			Choking	7	0	6	
			Choking sensation	1	0	1	
			Dry throat	1	0	1	
			Oropharyngeal pain	9	1	9	
			Rhinorrhoea	2	0	2	
			Throat tightness	2	0	2	
			Nasal congestion	3	0	3	
			Epistaxis	2	0	2	
			Sinus disorder	1	0	1	
			Pharyngeal oedema	1	0	1	
			Tonsillar disorder	2	0	2	
			<b>Respiratory, thoracic and mediastinal disorders</b>	<b>418</b>	<b>47</b>	<b>347</b>	
			Skin and subcutaneous tissue disorders	Angioedema	1	0	0
				Periorbital oedema	4	0	3
				Urticaria	7	0	5
		Lichenoid keratosis		1	0	1	

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Skin and subcutaneous tissue disorders</b>	Skin discolouration	1	0	1
			Skin disorder	1	0	0
			Skin odour abnormal	2	0	2
			Swelling face	3	0	2
			Dermatitis allergic	1	0	1
			Eczema	2	0	2
			Drug eruption	2	0	2
			Erythema	2	0	0
			Rash erythematous	7	0	7
			Dermatitis exfoliative generalised	1	0	1
			Rash papular	1	0	1
			Photosensitivity reaction	2	0	1
			Pruritus	14	0	14
			Psoriasis	2	0	1
			Rash	34	0	28
			Rash generalised	1	1	0
			Rash macular	1	0	1
			Rash maculo-papular	17	0	13
			Rash morbilliform	1	0	0
			Rash vesicular	1	0	1
			Systemic lupus erythematosus rash	1	0	1
			Erythema nodosum	1	0	1
			Acne	3	0	2
			Alopecia	6	0	5
			Cold sweat	4	0	3
			Hyperhidrosis	91	2	71
			Night sweats	2	0	2
			Sweat gland disorder	1	0	1
		Hirsutism	1	0	0	
		Purpura	3	0	3	
		<b>Skin and subcutaneous tissue disorders</b>	<b>222</b>	<b>3</b>	<b>176</b>	
		<b>Social circumstances</b>	Activities of daily living impaired	1	0	1
			Treatment noncompliance	15	0	13
			Social circumstances	16	0	14
		<b>Surgical and medical procedures</b>	Appendectomy	1	0	1
			Drug therapy changed	2	0	2
			Therapy regimen changed	6	0	4
			Surgical and medical procedures	9	0	7
		<b>Vascular disorders</b>	Aortic stenosis	2	0	2
			Necrosis ischaemic	2	1	2
			Peripheral ischaemia	2	0	2
			Blood pressure fluctuation	14	0	14

## clozapine to end January 2009

Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		<b>Vascular disorders</b>	<b>Circulatory collapse</b>	14	2	11
			<b>Shock</b>	7	3	4
			<b>Hypotension</b>	119	4	95
			<b>Orthostatic hypotension</b>	68	0	56
			<b>Cardiovascular insufficiency</b>	1	0	0
			<b>Embolism</b>	6	1	5
			<b>Thrombosis</b>	1	0	1
			<b>Venous thrombosis</b>	1	1	1
			<b>Deep vein thrombosis</b>	10	6	7
			<b>Thrombophlebitis</b>	3	0	2
			<b>Flushing</b>	5	0	5
			<b>Pallor</b>	19	0	17
			<b>Aortic dilatation</b>	1	0	1
			<b>Haemorrhage</b>	3	1	2
			<b>Hypertension</b>	85	1	77
			<b>Arteritis</b>	1	0	0
			<b>Vascular disorders</b>	364	20	304
		<b>Reaction</b>		11136	648	9390