

Medicine summary -sertraline (to end January 2009)

			Case Group	Death Outcomes	Sole
Case Count			5190	42	4393
Reaction Count	Blood and lymphatic system disorders	Anaemia	6	0	5
		Hypochromic anaemia	1	0	1
Microcytic anaemia		1	0	1	
Normochromic normocytic anaemia		1	0	0	
Aplastic anaemia		1	0	1	
Pancytopenia		3	0	0	
Coagulopathy		1	0	0	
Haemolytic anaemia		1	0	0	
Platelet disorder		3	0	3	
Thrombocytosis		2	0	0	
Thrombocytopenia		9	0	7	
Lymphadenopathy		3	0	3	
Eosinophilia		4	0	0	
Leukocytosis		7	1	3	
Neutrophilia		1	0	0	
Leukopenia		7	1	4	
Lymphopenia		1	0	0	
Agranulocytosis		2	0	1	
Neutropenia		9	0	4	
		Blood and lymphatic system disorders	63	2	33
	Cardiac disorders	Atrioventricular block	3	0	2
		Conduction disorder	1	0	1
		Arrhythmia	9	2	5
		Bradycardia	8	0	3
		Extrasystoles	4	0	3
		Tachycardia	48	0	29
		Atrial fibrillation	7	0	4
		Sinus tachycardia	2	0	1
		Supraventricular tachycardia	1	0	0
		Cardiac arrest	4	2	1
		Ventricular tachycardia	3	1	2
		Cardiac disorder	1	0	0
		Cyanosis	2	0	2
		Palpitations	105	0	86
		Mitral valve incompetence	2	0	1
		Coronary artery occlusion	1	0	1
		Angina pectoris	1	0	1
		Myocardial infarction	2	0	0
		Cardiac failure	1	0	0
		Cardiac failure congestive	1	0	1
	Left ventricular failure	1	0	0	

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			Case Group	Death Outcomes	Sole
Reaction Count	Cardiac disorders	Cardiomyopathy	3	0	1
		Cardiomegaly	1	1	0
		Dilatation ventricular	2	0	0
		Myocarditis	2	0	0
		Cardiac disorders	215	6	144
	Congenital, familial and genetic disorders	Heart disease congenital	3	0	2
		Cytogenetic abnormality	1	0	1
		Multiple congenital abnormalities	5	1	3
		Cleft palate	1	0	1
		Congenital foot malformation	1	0	0
		Congenital hand malformation	1	0	0
		Limb reduction defect	1	0	1
		Polydactyly	1	0	1
		Congenital hydrocephalus	1	0	1
		Tourette's disorder	2	0	2
		Hypospadias	1	0	0
		Pulmonary malformation	1	0	1
		Congenital, familial and genetic disorders	19	1	13
		Ear and labyrinth disorders	Ear pain	3	0
	Deafness		14	0	11
	Deafness neurosensory		1	0	1
	Hypoacusis		1	0	0
	Hyperacusis		4	0	3
	Inner ear disorder		3	0	3
	Motion sickness		1	0	1
	Tinnitus		24	0	21
	Vertigo		19	0	18
	Vertigo positional		1	0	1
	Otosclerosis		1	0	1
	Tympanic membrane hyperaemia		1	0	0
	Ear and labyrinth disorders		73	0	63
	Endocrine disorders		Cushing's syndrome	1	0
		Hyperprolactinaemia	14	0	11
		Inappropriate antidiuretic hormone secretion	28	0	22
		Hyperparathyroidism	1	0	1
		Goitre	1	0	1
		Thyroid disorder	1	0	1
		Hypothyroidism	5	0	2
		Endocrine disorders	51	0	38
	Eye disorders	Cataract	3	0	2
		Xerophthalmia	4	0	4
		Lacrimal disorder	2	0	2

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			Case Group	Death Outcomes	Sole		
Reaction Count	Eye disorders	Lacrimation increased	1	0	1		
		Eye disorder	3	0	3		
		Eye pain	8	0	6		
		Ocular discomfort	1	0	1		
		Retinal disorder	2	0	2		
		Angle closure glaucoma	1	0	1		
		Glaucoma	9	0	7		
		Hyphaema	1	0	1		
		Conjunctival haemorrhage	1	0	1		
		Optic ischaemic neuropathy	1	0	1		
		Conjunctivitis	6	0	5		
		Blepharospasm	1	0	0		
		Eye movement disorder	1	0	1		
		Oculogyric crisis	3	0	3		
		Miosis	1	0	0		
		Mydriasis	11	0	8		
		Eye rolling	2	0	0		
		Photophobia	8	0	6		
		Macular degeneration	1	0	0		
		Retinal degeneration	1	0	0		
		Exophthalmos	1	0	1		
		Retinal haemorrhage	1	0	1		
		Blindness	1	0	1		
		Night blindness	1	0	1		
		Sudden visual loss	1	0	1		
		Visual acuity reduced	4	0	3		
		Accommodation disorder	8	0	8		
		Diplopia	7	0	5		
		Scintillating scotoma	1	0	1		
		Vision blurred	10	1	9		
		Visual impairment	67	1	59		
			Eye disorders		174	2	145
		Gastrointestinal disorders		Hiatus hernia	1	0	1
				Proctalgia	1	0	1
				Anal inflammation	1	0	1
				Rectal tenesmus	1	0	1
Dental caries	2			0	2		
Sensitivity of teeth	1			0	1		
Toothache	1			0	1		
Gingival atrophy	1			0	1		
Gingival hyperplasia	2			0	2		
Gingivitis	1			0	1		

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Reaction Count		Case Group	Death Outcomes	Sole	
	Gastrointestinal disorders	Gingival bleeding	2	0	2
		Pancreatitis	5	0	3
		Pancreatitis acute	2	0	0
		Gastrointestinal disorder	3	0	3
		Hyperchlorhydria	1	0	1
		Rectal haemorrhage	5	0	5
		Gastrointestinal haemorrhage	1	1	0
		Haematemesis	1	0	1
		Melaena	3	0	0
		Upper gastrointestinal haemorrhage	1	0	1
		Colitis	7	0	7
		Gastritis	3	0	2
		Oesophagitis	5	0	4
		Reflux oesophagitis	2	0	2
		Diarrhoea	321	1	285
		Diarrhoea neonatal	1	0	1
		Constipation	17	0	14
		Gastrooesophageal reflux disease	4	0	4
		Impaired gastric emptying	1	0	0
		Oesophageal spasm	4	0	4
		Dyspepsia	45	1	41
		Eructation	3	0	3
		Abdominal distension	1	0	0
		Flatulence	11	0	10
		Abdominal pain	93	0	72
		Abdominal pain upper	6	0	5
		Oesophageal pain	1	0	1
		Abdominal discomfort	1	0	1
		Dysphagia	18	0	16
		Faecal incontinence	4	0	4
		Nausea	559	1	505
		Retching	2	0	2
		Vomiting	173	1	144
		Vomiting neonatal	2	0	2
		Intestinal obstruction	1	0	1
		Oesophageal stenosis	1	0	0
		Duodenal ulcer	3	0	0
		Duodenal ulcer haemorrhage	3	0	1
		Gastric ulcer	1	0	0
		Gastric ulcer haemorrhage	1	0	0
		Oesophagitis ulcerative	1	0	0
		Peptic ulcer haemorrhage	1	0	1

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			Case Group	Death Outcomes	Sole
Reaction Count	Gastrointestinal disorders	Coeliac disease	1	0	1
		Cheilitis	2	0	2
		Lip oedema	1	0	1
		Lip swelling	2	0	0
		Palatal disorder	1	0	1
		Aphthous stomatitis	1	0	1
		Mouth ulceration	14	0	14
		Stomatitis	1	0	1
		Ascites	1	1	0
		Dry mouth	49	1	43
		Salivary hypersecretion	15	1	12
		Glossitis	7	0	7
		Tongue disorder	3	0	2
		Tongue ulceration	2	0	2
		Swollen tongue	2	0	1
		Tongue discolouration	1	0	1
		Tongue oedema	4	0	4
		Gastrointestinal disorders	1439	8	1253
		General disorders and administration site conditions	Fever neonatal	1	0
	Hyperpyrexia		1	0	0
	Pyrexia		40	0	22
	Death		4	4	1
	Death neonatal		1	0	1
	Sudden death		9	9	2
	Asthenia		42	0	30
	Chronic fatigue syndrome		1	0	1
	Fatigue		116	1	102
	Malaise		77	1	57
	Gait disturbance		18	0	15
Condition aggravated	1		0	0	
General physical health deterioration	1		0	1	
Influenza like illness	8		0	7	
Irritability	6		0	6	
Face oedema	22		0	17	
Gravitational oedema	4		0	2	
Oedema	9		1	5	
Oedema peripheral	6		0	6	
Chest pain	52		0	36	
Discomfort	1	0	1		
Pain	32	0	28		
Chest discomfort	2	0	1		
Chills	27	0	16		

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			Case Group	Death Outcomes	Sole	
Reaction Count	General disorders and administration site conditions	Feeling abnormal	7	1	7	
		Feeling cold	1	0	1	
		Thirst	6	0	5	
		Drug interaction	4	1	0	
		Drug ineffective	81	5	67	
		Drug tolerance increased	1	0	1	
		Therapeutic response decreased	3	0	1	
		Therapeutic response unexpected	11	0	11	
		Therapeutic response unexpected with drug substitution	8	0	8	
		Drug withdrawal syndrome	10	0	10	
		Drug withdrawal syndrome neonatal	8	0	6	
			General disorders and administration site conditions	621	23	475
Reaction Count	Hepatobiliary disorders	Biliary colic	1	0	1	
		Cholangitis	1	0	1	
		Cholelithiasis	3	0	3	
		Cholestasis	1	0	1	
		Hepatitis cholestatic	5	0	4	
		Hyperbilirubinaemia	1	0	0	
		Jaundice	18	2	12	
		Hepatic function abnormal	57	1	33	
		Hepatic failure	3	2	2	
		Hepatic cirrhosis	2	1	0	
		Hepatomegaly	2	0	0	
		Hepatosplenomegaly	2	0	0	
		Hepatic necrosis	1	1	0	
		Hepatitis	16	0	8	
		Hepatocellular injury	2	0	1	
			Hepatobiliary disorders	115	7	66
		Reaction Count	Immune system disorders	Hypersensitivity	3	0
Serum sickness	1			0	1	
Drug hypersensitivity	1			0	1	
Anaphylactic reaction	2			0	1	
Anaphylactoid reaction	2			0	2	
	Immune system disorders			9	0	8
Reaction Count	Infections and infestations	Folliculitis	1	0	1	
		Pyomyositis	1	0	1	
		Candidiasis	2	0	2	
		Fungal infection	1	0	0	
		Diverticulitis	1	0	1	
		Meningitis	2	0	2	

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		Case Group	Death Outcomes	Sole	
Reaction Count	Infections and infestations	Meningitis aseptic	1	0	0
		Labyrinthitis	1	0	0
		Otitis media	2	0	1
		Lower respiratory tract infection	1	0	1
		Pneumonia	4	2	1
		Sepsis	1	1	0
		Rash pustular	4	0	3
		Laryngitis	1	0	1
		Pharyngitis	6	0	5
		Rhinitis	6	0	5
		Sinusitis	2	0	2
		Cystitis	1	0	1
		Urinary tract infection	7	0	5
		Herpes simplex	2	0	2
		Viral infection	1	0	0
		Infections and infestations	48	3	34
	Injury, poisoning and procedural complications	Drug toxicity	1	1	0
		Therapeutic agent toxicity	1	0	0
		Drug exposure during pregnancy	10	0	9
		Fall	11	0	6
		Wound haemorrhage	1	0	0
		Contusion	4	0	4
		Drug administration error	1	0	1
		Medication error	2	0	2
		Accidental overdose	1	0	1
		Intentional overdose	7	2	4
		Overdose	7	0	3
		Post procedural haemorrhage	1	0	1
		Injury, poisoning and procedural complications	47	3	31
	Investigations	Electrocardiogram abnormal	6	0	1
		Heart rate increased	1	0	1
		Blood pressure decreased	4	0	2
		Blood pressure increased	4	0	4
		Glucocorticoids increased	1	0	0
Blood prolactin increased		1	0	0	
Blood thyroid stimulating hormone decreased		1	0	1	
Thyroid function test abnormal		1	0	1	
Blood creatine phosphokinase increased		14	1	5	
Blood alkaline phosphatase increased		1	0	1	
Blood amylase increased		2	0	0	
Lipase increased	1	0	0		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Investigations	Bleeding time prolonged	3	0	3	
		Prothrombin level decreased	8	0	1	
		Red blood cell sedimentation rate increased	1	0	1	
		Alanine aminotransferase increased	1	0	0	
		Aspartate aminotransferase increased	2	0	1	
		Gamma-glutamyltransferase increased	3	0	2	
		Hepatic enzyme abnormal	1	0	1	
		Hepatic enzyme increased	1	0	1	
		Liver function test abnormal	9	1	7	
		Antinuclear antibody increased	1	0	1	
		Laboratory test abnormal	1	0	1	
		Blood cholesterol increased	1	0	0	
		Blood folate decreased	1	0	1	
		CSF pressure increased	1	0	1	
		Electroencephalogram abnormal	2	0	1	
		Nerve conduction studies abnormal	1	0	1	
		Apgar score low	2	0	2	
		Body temperature increased	1	0	0	
		Weight decreased	42	0	34	
		Weight increased	81	1	72	
		Blood albumin decreased	1	0	1	
		C-reactive protein increased	1	0	1	
		Globulins increased	1	0	1	
		Blood creatinine decreased	1	0	1	
		Blood creatinine increased	1	0	1	
		Blood urine present	1	0	0	
		Semen analysis abnormal	1	0	1	
		Drug level above therapeutic	1	0	0	
		Drug level decreased	2	0	0	
		Drug level increased	16	2	0	
		Blood sodium decreased	5	0	4	
		Blood osmolarity decreased	1	0	0	
		Urine osmolarity decreased	1	0	0	
			Investigations	233	5	157
		Metabolism and nutrition disorders	Ketosis	1	0	1
			Metabolic acidosis	1	0	0
			Acidosis	3	0	2
Decreased appetite	51		2	42		
Increased appetite	12		0	10		
Failure to thrive	1		0	1		
Feeding disorder neonatal	2		0	2		
Hypocalcaemia	1		0	0		

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			Case Group	Death Outcomes	Sole	
Reaction Count	Metabolism and nutrition disorders	Tetany	6	0	5	
		Hypermagnesaemia	1	0	1	
		Hypochloraemia	2	0	2	
		Electrolyte imbalance	1	0	1	
		Oligodipsia	1	0	1	
		Polydipsia	2	0	2	
		Hyperkalaemia	2	0	0	
		Hypokalaemia	10	1	6	
		Hypernatraemia	6	0	4	
		Hyponatraemia	186	3	123	
		Dehydration	6	0	4	
		Hypovolaemia	1	0	0	
		Alcohol intolerance	8	0	5	
		Lactose intolerance	1	0	1	
		Diabetes mellitus	4	0	4	
		Hyperglycaemia	7	0	7	
		Hypoglycaemia	15	0	10	
		Hyperlipidaemia	1	0	1	
		Hypoproteinaemia	1	0	0	
		Gout	1	0	1	
		Metabolism and nutrition disorders	334	6	236	
		Musculoskeletal and connective tissue disorders	Bone pain	2	0	2
			Pain in jaw	3	0	3
			Osteoporosis	1	0	1
			Collagen disorder	2	0	2
			Scleroderma	1	0	1
			Systemic lupus erythematosus	2	0	1
			Arthritis	4	0	4
			Arthralgia	34	0	26
	Joint stiffness		1	0	0	
	Joint swelling		1	0	1	
	Osteoarthritis		5	0	4	
	Myalgia		55	0	46	
	Muscle spasms		20	0	14	
	Muscle tightness		1	0	1	
	Muscle twitching		63	0	48	
	Hypotonia neonatal		3	0	3	
	Muscle rigidity		7	0	4	
	Trismus		1	0	1	
	Muscular weakness		5	0	4	
	Myopathy		1	0	0	
	Rhabdomyolysis	5	0	3		

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Reaction Count			Case Group	Death Outcomes	Sole
	Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	5	0	2
		Sensation of heaviness	1	0	1
		Back pain	11	0	8
		Neck pain	2	0	1
		Pain in extremity	1	0	1
		Bursitis	2	0	2
		Tendonitis	1	0	1
		Musculoskeletal and connective tissue disorders	240	0	185
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatic neoplasm malignant	1	1	1
		Leukaemia	1	0	0
		Hairy cell leukaemia	1	0	0
		Lymphoma	1	0	1
		Metastasis	1	0	1
		Paraproteinaemia	1	0	1
		Sarcoma	2	0	2
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8	1	6
	Nervous system disorders	Cerebral haemorrhage	3	1	0
		Cerebrovascular accident	2	0	2
		Haemorrhage intracranial	1	0	0
		Cerebrovascular disorder	4	2	3
		Facial palsy	3	0	3
		Facial spasm	1	0	0
		Tongue paralysis	1	0	0
		Parosmia	3	0	2
		Encephalopathy	2	1	1
		Headache	297	0	262
		Tension headache	3	0	2
		Migraine	27	0	24
		Brain oedema	1	1	0
		Intracranial pressure increased	1	0	1
		Dementia	2	0	0
		Amnesia	51	0	41
		Memory impairment	1	0	0
Cognitive disorder		5	0	2	
Disturbance in attention		27	1	23	
Mental impairment		2	0	1	
Choreoathetosis		5	0	3	
Akathisia	16	0	11		
Bradykinesia	1	0	1		
Dyskinesia	40	0	30		

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	Nervous system disorders	Extrapyramidal disorder	18	1	12
		Hyperkinesia	37	0	27
		Hypokinesia	8	0	7
		Movement disorder	1	0	1
		Psychomotor hyperactivity	2	0	2
		Tardive dyskinesia	6	0	5
		Dystonia	55	0	40
		Hemiparesis	4	0	2
		Paralysis	3	0	3
		Paresis	3	0	3
		Parkinsonism	1	0	0
		Tremor	249	1	193
		Tremor neonatal	1	0	1
		Hyperreflexia	11	0	4
		Hyporeflexia	1	0	0
		Reflexes abnormal	1	0	1
		Ataxia	30	0	25
		Balance disorder	1	0	1
		Coordination abnormal	17	0	13
		Nystagmus	6	0	3
		Coma	10	2	5
		Aphasia	5	0	5
		Consciousness fluctuating	7	0	1
		Depressed level of consciousness	1	0	1
		Lethargy	9	0	7
		Loss of consciousness	5	0	4
		Sedation	1	0	0
		Somnolence	131	1	114
		Somnolence neonatal	2	0	2
		Stupor	3	0	3
		Syncope	64	2	48
		Central nervous system lesion	1	0	0
		Clonus	1	0	0
		Dizziness	296	0	260
		Myoclonus	4	0	1
		Neurological symptom	1	0	0
		Presyncope	1	0	1
		Unresponsive to stimuli	1	0	0
		Crying	9	0	8
		Burning sensation	5	0	5
	Formication	3	0	3	
	Hyperaesthesia	7	0	5	

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Reaction Count	Nervous system disorders	Paraesthesia	107	0	96	
		Ageusia	3	0	1	
		Dysgeusia	12	0	11	
		Hypoaesthesia	37	0	32	
		Neuralgia	1	0	1	
		Restless legs syndrome	2	0	2	
		Sensory disturbance	9	0	9	
		Dysarthria	12	0	8	
		Incoherent	1	0	0	
		Speech disorder	19	0	15	
		Visual field defect	5	0	4	
		Hypertonia	62	0	42	
		Hypotonia	1	0	1	
		Neuroleptic malignant syndrome	8	0	0	
		Serotonin syndrome	82	0	29	
		Muscle contractions involuntary	3	0	2	
		Muscle spasticity	1	0	0	
		Guillain-Barre syndrome	1	0	0	
		Peroneal nerve palsy	1	0	1	
		Neuropathy peripheral	3	0	3	
		Convulsion neonatal	2	0	1	
		Grand mal convulsion	32	1	18	
		Convulsion	138	3	95	
		Convulsive threshold lowered	1	0	0	
		Epilepsy	4	0	4	
		Tonic convulsion	1	0	0	
		Hypersomnia	2	0	1	
		Poor quality sleep	3	0	3	
		Nerve root lesion	1	0	1	
			Nervous system disorders	2075	17	1608
		Pregnancy, puerperium and perinatal conditions	Abortion	2	0	2
			Abortion spontaneous	7	0	5
			Intra-uterine death	9	1	8
			Stillbirth	1	0	1
Foetal distress syndrome	1		0	0		
Labour onset delayed	1		0	1		
Premature labour	1		0	1		
Premature rupture of membranes	2		0	2		
Premature separation of placenta	1		0	1		
Ectopic pregnancy	1		0	1		
Neonatal disorder	12		0	7		
Postpartum haemorrhage	1		0	1		

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			Case Group	Death Outcomes	Sole
Reaction Count	Pregnancy, puerperium and perinatal conditions	Unintended pregnancy	2	0	0
		Pregnancy, puerperium and perinatal conditions	41	1	30
	Psychiatric disorders	Agitation	428	2	367
		Agitation neonatal	7	0	7
		Anxiety	207	0	184
		Nervousness	29	0	18
		Stress	3	1	2
		Fear	1	0	1
		Panic attack	9	0	8
		Panic reaction	2	0	2
		Post-traumatic stress disorder	1	0	0
		Neurosis	27	0	21
		Obsessive thoughts	2	0	2
		Obsessive-compulsive disorder	3	0	2
		Catonia	2	0	2
		Restlessness	9	0	4
		Automatism	2	0	1
		Bruxism	47	0	44
		Tic	2	0	2
		Change in sustained attention	1	0	1
		Reading disorder	1	0	1
		Screaming	2	0	2
		Confusional state	149	1	87
		Disorientation	7	0	6
		Delirium	25	0	16
		Agitated depression	1	0	1
		Depression	61	2	42
		Depressed mood	3	0	3
		Tearfulness	4	0	3
		Depersonalisation	72	0	66
		Dissociation	1	0	1
		Delusion	14	0	11
		Thought insertion	1	0	1
		Hallucination	81	0	58
		Hallucination, auditory	4	0	3
		Hallucination, visual	5	0	1
Hallucinations, mixed	1	0	0		
Tachyphrenia	1	0	1		
Thinking abnormal	41	0	31		
Eating disorder	2	0	1		
Compulsive shopping	1	0	1		

Medicine summary -sertraline (to end January 2009)

Reaction Count	Psychiatric disorders		Case Group	Death Outcomes	Sole
		Pathological gambling	1	0	1
		Bipolar disorder	1	0	1
		Hypomania	2	0	2
		Mania	54	0	46
		Affect lability	22	0	19
		Anger	4	0	3
		Emotional disorder	1	0	1
		Emotional distress	2	0	2
		Euphoric mood	13	0	11
		Mood altered	1	0	0
		Mood swings	9	1	7
		Apathy	9	1	7
		Aggression	69	0	46
		Homicidal ideation	9	0	6
		Paranoia	23	1	12
		Personality change	4	1	2
		Social avoidant behaviour	1	1	0
		Violence-related symptom	3	0	2
		Personality disorder	3	0	1
		Abnormal behaviour	3	0	2
		Staring	1	0	1
		Hypervigilance	1	0	1
		Mental disorder	3	0	1
		Mental status changes	1	0	1
		Alcoholism	3	0	2
		Drug dependence	3	0	3
		Withdrawal syndrome	205	0	188
		Delusional disorder, unspecified type	1	0	0
		Acute psychosis	1	0	1
		Psychotic disorder	39	0	29
		Schizophreniform disorder	3	0	2
		Schizophrenia	1	0	1
		Anorgasmia	60	0	57
		Libido decreased	139	0	129
		Libido increased	6	0	6
		Loss of libido	3	1	1
		Insomnia	249	1	225
		Abnormal dreams	11	0	9
		Abnormal sleep-related event	1	0	1
		Nightmare	55	0	47
		Somnambulism	3	0	3
		Sleep disorder	15	0	14

Medicine summary -sertraline (to end January 2009)

			Case Group	Death Outcomes	Sole
Reaction Count	Psychiatric disorders	Conversion disorder	1	0	1
		Completed suicide	7	7	5
		Intentional self-injury	4	0	3
		Self injurious behaviour	3	0	3
		Self-injurious ideation	1	0	1
		Suicidal behaviour	4	1	3
		Suicidal ideation	51	0	42
		Suicide attempt	56	6	42
		Psychiatric disorders	2424	27	1997
	Renal and urinary disorders	Glomerulonephritis	1	0	0
		Nephrotic syndrome	1	0	1
		Tubulointerstitial nephritis	1	0	0
		Oliguria	1	0	1
		Renal failure	2	0	1
		Renal failure acute	5	0	0
		Renal failure chronic	1	0	0
		Renal impairment	7	0	4
		Bladder spasm	1	0	1
		Dysuria	9	0	7
		Enuresis	1	0	1
		Micturition disorder	13	0	11
		Micturition urgency	1	0	1
		Pollakiuria	17	0	16
		Urinary hesitation	1	0	1
		Urinary incontinence	25	1	21
		Urinary retention	24	0	21
		Albuminuria	2	0	1
		Haematuria	7	0	5
		Nocturia	8	0	8
		Polyuria	2	0	2
		Renal pain	2	0	2
		Nephrolithiasis	1	0	1
		Calculus bladder	1	0	0
Renal and urinary disorders	134	1	106		
Reproductive system and breast disorders	Breast calcifications	1	0	0	
	Breast enlargement	5	0	3	
	Breast mass	4	0	3	
	Gynaecomastia	7	0	6	
	Breast engorgement	1	0	1	
	Breast pain	9	0	9	
	Galactorrhoea	31	0	26	
	Suppressed lactation	8	0	7	

Medicine summary -sertraline (to end January 2009)

			Case Group	Death Outcomes	Sole
Reaction Count	Reproductive system and breast disorders	Atrophic vulvovaginitis	2	0	2
		Menstrual disorder	12	0	10
		Metrorrhagia	19	0	17
		Amenorrhoea	7	0	5
		Menorrhagia	14	0	12
		Ovarian cyst	1	0	1
		Penis disorder	1	0	1
		Prostatic disorder	1	0	1
		Genital discharge	1	0	0
		Perineal pain	3	0	3
		Ejaculation delayed	1	0	1
		Ejaculation disorder	3	0	3
		Ejaculation failure	91	0	88
		Erectile dysfunction	62	0	61
		Priapism	6	0	4
		Dyspareunia	2	0	2
		Infertility female	2	0	2
		Sexual dysfunction	35	0	34
		Azoospermia	1	0	1
		Testicular disorder	2	0	2
		Uterine disorder	1	0	1
		Uterine haemorrhage	7	0	7
		Uterine pain	1	0	1
		Vaginal haemorrhage	19	0	17
		Vulval disorder	2	0	2
		Vulvovaginal pain	1	0	1
			Reproductive system and breast disorders		363
Reaction Count	Respiratory, thoracic and mediastinal disorders	Asthma	2	0	2
		Bronchospasm	12	0	10
		Wheezing	1	0	1
		Pneumonitis	2	0	2
		Pulmonary oedema	1	0	1
		Infantile apnoeic attack	1	0	1
		Neonatal respiratory depression	2	0	2
		Pulmonary hypertension	2	0	0
		Pulmonary embolism	3	0	1
		Apnoea	2	0	2
		Dyspnoea	51	0	34
		Hyperventilation	9	0	7
		Respiratory arrest	1	0	1
		Tachypnoea	1	0	0
		Asphyxia	1	1	1

Medicine summary -sertraline (to end January 2009)

		Case Group	Death Outcomes	Sole	
Reaction Count	Respiratory, thoracic and mediastinal disorders	Hypoxia	1	0	1
		Cough	15	0	15
		Haemoptysis	1	0	1
		Sputum increased	1	0	1
		Hiccups	2	0	2
		Pleuritic pain	1	0	0
		Respiratory failure	1	1	0
		Respiratory disorder	4	0	3
		Choking	1	0	1
		Dysphonia	2	0	2
		Oropharyngeal pain	2	0	2
		Throat irritation	1	0	0
		Throat tightness	7	0	5
		Yawning	43	0	40
		Stridor	1	0	1
		Nasal congestion	1	0	1
		Epistaxis	21	0	17
		Pharyngeal oedema	2	0	2
		Respiratory, thoracic and mediastinal disorders	198	2	159
	Skin and subcutaneous tissue disorders	Angioedema	10	0	6
		Periorbital oedema	6	0	6
		Urticaria	50	0	44
		Lichenoid keratosis	3	0	2
		Skin atrophy	1	0	0
		Dermatitis bullous	8	0	8
		Erythema multiforme	7	0	4
		Stevens-Johnson syndrome	2	0	0
		Dry skin	8	0	7
		Hypoaesthesia facial	1	0	1
Skin burning sensation		1	0	0	
Skin discolouration		4	0	4	
Skin disorder		2	0	1	
Skin odour abnormal		2	0	2	
Swelling face		4	0	3	
Yellow skin		1	0	1	
Dermatitis		1	0	1	
Dermatitis allergic		1	0	1	
Eczema		3	0	2	
Neurodermatitis	1	0	1		
Drug eruption	1	0	1		
Rash erythematous	35	0	31		

Medicine summary -sertraline (to end January 2009)

			Case Group	Death Outcomes	Sole	
Reaction Count	Skin and subcutaneous tissue disorders	Dermatitis exfoliative	1	0	0	
		Exfoliative rash	1	0	1	
		Skin exfoliation	9	0	9	
		Rash papular	1	0	1	
		Photosensitivity reaction	18	0	15	
		Pruritus	104	1	90	
		Rash pruritic	4	0	3	
		Dermatitis psoriasiform	1	0	1	
		Psoriasis	3	0	3	
		Pustular psoriasis	1	0	1	
		Rash follicular	1	0	0	
		Rash	157	0	141	
		Rash macular	1	0	0	
		Rash maculo-papular	48	0	38	
		Rash morbilliform	2	0	2	
		Rash vesicular	3	0	3	
		Chloasma	1	0	1	
		Erythema nodosum	6	0	6	
		Acne	23	0	18	
		Alopecia	40	0	34	
		Cold sweat	7	0	5	
		Hyperhidrosis	214	1	173	
		Night sweats	2	0	2	
		Hirsutism	1	0	1	
		Nail disorder	1	0	1	
		Hair texture abnormal	2	0	2	
		Ecchymosis	1	0	1	
		Increased tendency to bruise	2	0	1	
		Purpura	50	0	39	
			Skin and subcutaneous tissue disorders	857	2	718
		Social circumstances	Physical assault	1	0	1
			Social circumstances	1	0	1
		Surgical and medical procedures	Drug therapy changed	20	0	20
Therapy regimen changed	14		0	12		
Surgical and medical procedures	34		0	32		
Vascular disorders	Aortic stenosis	1	0	1		
	Ischaemia	1	0	1		
	Peripheral ischaemia	2	0	1		
	Peripheral coldness	1	0	1		
	Blood pressure fluctuation	1	0	0		
	Circulatory collapse	7	0	4		
	Hypotension	28	1	13		

Medicine summary -sertraline (to end January 2009)

			Case Group	Death Outcomes	Sole
Reaction Count	Vascular disorders	Orthostatic hypotension	25	0	19
		Thrombosis	2	0	2
		Deep vein thrombosis	2	0	1
		Vasodilatation	2	0	2
		Vein disorder	1	0	1
		Flushing	56	0	48
		Hot flush	26	0	21
		Pallor	3	0	3
		Haematoma	2	0	1
		Haemorrhage	6	0	5
		Hypertension	42	0	32
		Vasculitis	1	0	0
		Vascular disorders	209	1	156
		Reaction		10025	118