Appendix 8: Community Exceptional Circumstances Applications Approved Between 2001–2009

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
31/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
31/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
31/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
31/08/2009	Awaiting more information on application	Letter, but no actual application	solifenacin	urge incontinence	Urge incontinence of urine	Genito-urinary system
31/08/2009	Awaiting more information on application	Letter, but no actual application	orlistat	Morbid Obesity		Alimentary tract and metabolism
28/08/2009	Declined application		tramadol	chronic neuropathic pain, PTSD, depression		Nervous system
28/08/2009	Awaiting more information on application		buprenorphine (Suboxone)	opioid dependence and QT prolongation, prolonged QT		Nervous system
28/08/2009	Declined application		levonorgestrel (Mirena)	platelet dysfunction	Platelet disorder	Hormone preps-systemic excl contraceptive hormones
28/08/2009	Declined application	Transferred to Hospital EC	moxifloxacin	pulmonary tuberculosis		Infections - agents for systemic use
28/08/2009	Declined application		Cinacalcet	end stage renal failure, Tertiary hyperparathyroidism	Tertiary hyperparathyroidism	Hormone preps-systemic excl contraceptive hormones
28/08/2009	Awaiting more		alglucosidase	pompe disease	Lysosomal alpha-	Alimentary tract and metabolism

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	information on application		alfa (Myozyme)		1,4-glucosidase deficiency - infantile onset	
28/08/2009	Awaiting more information on application		alglucosidase alfa (Myozyme)	pompe disease		Alimentary tract and metabolism
27/08/2009	Automatic renewal of authority		propylthiouracil	breast feeding		Hormone preps-systemic excl contraceptive hormones
27/08/2009	Automatic renewal of authority		propylthiouracil	rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
27/08/2009	Declined application		amlodipine (Norvasc)	Hypertension		Cardiovascular system
27/08/2009	Declined application	Transferred to Hospital EC	ketocal vanilla	neurological condition		Special foods
27/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash on funded carbimazole		Hormone preps-systemic excl contraceptive hormones
27/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
26/08/2009	Approved renewal of authority		thalidomide	nodular prurigo	Prurigo nodularis	Dermatologicals
26/08/2009	Approved renewal of authority		idebenone	Friedreich's Ataxia	Cardiomyopathy in Friedreich's ataxia	Cardiovascular system
26/08/2009	Awaiting more information on application		methyl prednisolone	corneal grafts, glaucoma		Sensory organs
26/08/2009	Approved renewal of authority		cinacalcet	hypercalcemia, primary hyperparathyroidism	Primary hyperparathyroidism	Hormone preps-systemic excl contraceptive hormones
26/08/2009	Approved initial application		amiloride	bilateral nodular adrenal hyperplasia, conn's		Cardiovascular system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
				syndrome		
26/08/2009	Awaiting more information on application		growth hormone	adult growth hormone deficiency		Hormone preps-systemic excl contraceptive hormones
26/08/2009	Approved initial application		sodium citrate	parenteral nutrition dependence		Alimentary tract and metabolism
26/08/2009	Declined application	Transferred to Hospital EC	lignocaine hydrochloride	chronic pain		Nervous system
26/08/2009	Approved renewal of authority		potassium citrate	distal renal tubular acidosis, Sjogrens syndrome	Renal tubular acidosis	Genito-urinary system
26/08/2009	Approved renewal of authority		imatinib mesylate (glivec)	chronic eosinophilic leukemia	Chronic eosinophilic leukaemia	Oncology agents and immunosuppressants
26/08/2009	Approved renewal of authority		pravastatin (Lipitor)	heart Transplant	Transplantation of heart	Blood and blood forming organs
26/08/2009	Approved renewal of authority		xlys low tryp maxamaid	glutaric aciduria type 1	Glutaric aciduria, type 1	Alimentary tract and metabolism
25/08/2009	Declined application		etoricoxib	Behcets Disease	Arthropathy in Behcet's syndrome	Nervous system
25/08/2009	Declined application	auto	oestradiol	Turner's syndrome		Hormone preps-systemic excl contraceptive hormones
25/08/2009	Automatic approval of initial application		Phenoxybenzamine	prostatism		Cardiovascular system
25/08/2009	Automatic approval of initial application		Phenoxybenzamine	paraganglioma	Paraganglioma	Cardiovascular system
25/08/2009	Declined application	Transferred to Hospital EC	moxifloxacin	pleural tuberculosis	Tuberculosis of pleura	Infections - agents for systemic use
24/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic reaction		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
21/08/2009	Declined application		mycophenolate	vasculitis	Vasculitis	Oncology agents and immunosuppressants
21/08/2009	Declined application		losartan	marfan syndrome	Marfan's syndrome	Cardiovascular system
21/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	Carbimazole intolerant		Hormone preps-systemic excl contraceptive hormones
21/08/2009	Declined application		loperamide		Ileostomy present	Alimentary tract and metabolism
21/08/2009	Automatic renewal of authority		propylthiouracil	impairment of LFT's		Hormone preps-systemic excl contraceptive hormones
21/08/2009	Declined application		tadalafil	CREST, Scleroderma, ulceration of digits	Ischemic finger	Cardiovascular system
21/08/2009	Approved renewal of authority		pipobroman	essential thrombocythemia/polycythemia	Essential thrombocythaemia	Blood and blood forming organs
21/08/2009	Declined application		atomoxetine	ADHD, ADHD, ODD	Attention deficit hyperactivity disorder	Nervous system
21/08/2009	Approved renewal of authority		uridine powder	Oroticaciduria, Oroticaciduria-metabolic disorder	Hereditary orotic aciduria	Musculo-skeletal system
21/08/2009	Declined application		voriconazole	aspergillus flavus	Aspergillus flavus	Infections - agents for systemic use
21/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	rash and vomiting with carbimazole		Hormone preps-systemic excl contraceptive hormones
21/08/2009	Declined application	Transferred to Hospital EC	valganciclovir	CMV, uveitis		Infections - agents for systemic use
21/08/2009	Automatic renewal of authority		propylthiouracil	rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
21/08/2009	Declined application		erythropoietin	diabetes Type 1, recurrent syncope	Diabetes mellitus type 1	Blood and blood forming organs
21/08/2009	Declined application		losartan	marfan syndrome	Marfan's syndrome	Cardiovascular system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
20/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	pregnant		Hormone preps-systemic excl contraceptive hormones
18/08/2009	Approved initial application	Board approval	idursulphase (Elaprase)	Hunter syndrome, Hunter's syndrome	Hunter's syndrome, severe form	Alimentary tract and metabolism
17/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash on funded carbimazole		Hormone preps-systemic excl contraceptive hormones
17/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	neutropaenia		Hormone preps-systemic excl contraceptive hormones
14/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	Currently pregnant		Hormone preps-systemic excl contraceptive hormones
12/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash on funded carbimazole		Hormone preps-systemic excl contraceptive hormones
12/08/2009	Automatic renewal of authority		propylthiouracil	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
12/08/2009	Automatic renewal of authority		propylthiouracil	allergic reaction to carbimazole		Hormone preps-systemic excl contraceptive hormones
11/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	Currently pregnant		Hormone preps-systemic excl contraceptive hormones
10/08/2009	Declined application		levetiracetam	spinal myoclonus		Nervous system
10/08/2009	Automatic renewal of authority		propylthiouracil	urticaria		Hormone preps-systemic excl contraceptive hormones
10/08/2009	Automatic approval of initial application		liothyronine (Tertroxin)	allergy to thyroxine		Hormone preps-systemic excl contraceptive hormones
10/08/2009	Awaiting more		trientine	Wilson's disease	Wilson's disease	Alimentary tract and metabolism

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	information on application		(Univar)			
7/08/2009	Automatic renewal of authority		liothyronine (Tertroxin)	resistance to tyroxine		Hormone preps-systemic excl contraceptive hormones
6/08/2009	Declined application		thyroid extract	Hypothyroidism		Hormone preps-systemic excl contraceptive hormones
5/08/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	developed drug induced hepatitis on carbimazole		Hormone preps-systemic excl contraceptive hormones
5/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	intending to become pregnant		Hormone preps-systemic excl contraceptive hormones
5/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash on funded carbimazole		Hormone preps-systemic excl contraceptive hormones
5/08/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
4/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	Breastfeeding, Carbimazole Contraindicted		Hormone preps-systemic excl contraceptive hormones
4/08/2009	Automatic renewal of authority		prednisolone sodium phosphate oral liquid (Redipred)	oral lichen planus		Dermatologicals
4/08/2009	Automatic renewal of authority		prednisolone sodium phosphate (Redipred)	Mucous membrane pemphigus, pemphigus of mouth		Dermatologicals
4/08/2009	Automatic approval of initial application	auto	propylthiouracil			Hormone preps-systemic excl contraceptive hormones
3/08/2009	Automatic renewal of		propylthiouracil	Breast Feeding so unable to tolerate		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	authority			Carbimazole		
3/08/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	breastfeeding and reaction on carbimazole		Hormone preps-systemic excl contraceptive hormones
3/08/2009	Approved renewal of authority	auto	amiloride	GI upset with slow K, renal transplant with Bartters syndrome	Pseudoprimary aldosteronism	Genito-urinary system
31/07/2009	Approved renewal of authority		l-carnitine	Medium Chain Acyl coA dehydrogenase deficency	Medium-chain acyl-coenzyme A dehydrogenase deficiency	Alimentary tract and metabolism
31/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
31/07/2009	Approved renewal of authority	auto	pimozide	chronic schizophrenia	Schizophrenia	Nervous system
30/07/2009	Declined application		tramadol	Osteoarthritis		Nervous system
30/07/2009	Declined application		atorvastatin (Lipitor)	hyperlipidaemia		Blood and blood forming organs
30/07/2009	Declined application		cinacalcet	end stage renal failure, Tertiary hyperparathyroidism	Tertiary hyperparathyroidism	Hormone preps-systemic excl contraceptive hormones
30/07/2009	Declined application		pravastatin	hyperlipidaemia, kidney transplant	Hyperlipidaemia	Blood and blood forming organs
30/07/2009	Declined application		donepezil hydrochloride	dementia	Dementia	Nervous system
30/07/2009	Approved initial application		diazoxide	Insulinoma		Hormone preps-systemic excl contraceptive hormones
29/07/2009	Approved renewal of authority		pravastatin	hypercholesterolemia, heart transplant, recurrent simvastatin related myopathy	Hypercholesterolemia	Blood and blood forming organs
29/07/2009	Declined renewal		paroxetine (Aropax)	Depression	Chronic depression	Nervous system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
29/07/2009	Approved renewal of authority		l-carnitine	Medium Chain Acyl coA dehydrogenase deficency	Medium-chain acyl-coenzyme A dehydrogenase deficiency	Alimentary tract and metabolism
29/07/2009	Declined application	Transferred to Hospital EC	potassium citrate	renal stones	Renal stone	Genito-urinary system
29/07/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	intending to become pregnant		Hormone preps-systemic excl contraceptive hormones
29/07/2009	Declined application		levetiracetam	spinal myoclonus		Nervous system
29/07/2009	Declined renewal		stiemycin topical anitbiotic	inflamed folliculitis	Folliculitis	Dermatologicals
29/07/2009	Approved renewal of authority		sirolimus	Lymphangioleiomyomatosis	Lymphangiomyomatosis	Oncology agents and immunosuppressants
29/07/2009	Approved renewal of authority		amiloride	Gitelman's syndrome, hypokalaemia	Familial hypokalaemia-hypomagnesaemia	Hormone preps-systemic excl contraceptive hormones
29/07/2009	Approved renewal of authority		pyridoxine	oxalosis	Oxalosis	Alimentary tract and metabolism
29/07/2009	Automatic renewal of authority		prednisolone sodium phosphate oral liquid (Redipred)	oral ulceration		Dermatologicals
29/07/2009	Approved renewal of authority		cyclosporin	serious aplastic anaemia	Aplastic anaemia	Oncology agents and immunosuppressants
29/07/2009	Approved renewal of authority		buprenorphine/naloxone (suboxone)	opioid dependence and QT prolongation	Prolonged QT interval	Nervous system
29/07/2009	Declined application	Transferred to Hospital EC	modafinil (Modavigil)	hypersomnia, psychotic disorder		Nervous system
29/07/2009	Approved		test strips	functioning	Insulinoma	Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	renewal of authority		(Optium)	pancreatic insulinoma metastatic to liver		
29/07/2009	Declined renewal		paroxetine (Aropax)	intolerance of alternates		Nervous system
29/07/2009	Approved renewal of authority		lorenzo's oil (glycerol trierucate, glycerol trioleate)	adrenoleukodystrophy	Adrenoleukodystrophy	Alimentary tract and metabolism
29/07/2009	Declined application		tacrolimus	severe atopic keratoconjunctivitis	Atopic keratoconjunctivitis	Sensory organs
28/07/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	allergic rash with carbimazole, pregnancy/ breast feeding		Hormone preps-systemic excl contraceptive hormones
28/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
28/07/2009	Automatic approval of initial application		prednisolone (Redipred)	Oral Lichem Planas		Dermatologicals
27/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
24/07/2009	Declined application	auto	paroxetine (Aropax)	Depression		Nervous system
24/07/2009	Declined renewal	auto	paroxetine (Aropax)	Anxiety and Depression	Chronic depression	Nervous system
24/07/2009	Declined renewal	auto	paroxetine (Aropax)	Bipolar Disorder, depression	Chronic depression	Nervous system
24/07/2009	Declined renewal	auto	paroxetine (Aropax)	Depression		Nervous system
24/07/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	recurrent thyrotoxious		Hormone preps-systemic excl contraceptive hormones
24/07/2009	Automatic renewal of		propylthiouracil	pregnancy/ breast feeding		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	authority		(Propylthiouracil)			
24/07/2009	Automatic renewal of authority		propylthiouracil	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
23/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	Graves disease, Hyperthyroidism		Hormone preps-systemic excl contraceptive hormones
22/07/2009	Awaiting more information on application	Letter, but no actual application	occuvite preservision	age realted macular degeneration		Sensory organs
22/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
22/07/2009	Automatic renewal of authority		liothyronine (Tertroxin)	Hypothyroidism, Poor symptom control on Thyrozine		Hormone preps-systemic excl contraceptive hormones
22/07/2009	Automatic renewal of authority		liothyronine (Tertroxin)	Intolerant of thyroxine		Hormone preps-systemic excl contraceptive hormones
22/07/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	pre pregnancy		Hormone preps-systemic excl contraceptive hormones
22/07/2009	Automatic approval of initial application		liothyronine (Tertroxin)	intolerence to all 3 available brands of Thyroxine		Hormone preps-systemic excl contraceptive hormones
17/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	trying to become pregnant		Hormone preps-systemic excl contraceptive hormones
17/07/2009	Automatic renewal of authority		liothyronine (Tertroxin)	Autoimmune hypothyroidism		Hormone preps-systemic excl contraceptive hormones
17/07/2009	Automatic approval of initial application		ethambutol (Ethambutol)			Infections - agents for systemic use

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
15/07/2009	Approved renewal of authority		amiloride	Gitelman's syndrome	Familial hypokalaemia-hypomagnesaemia	Alimentary tract and metabolism
15/07/2009	Declined renewal		paroxetine (Aropax)	depression and anxiety, side effects with loxamine		Nervous system
15/07/2009	Approved renewal of authority		diazoxide	functioning pancreatic insulinoma metastatic to liver	Insulinoma	Alimentary tract and metabolism
15/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
15/07/2009	Approved renewal of authority		minoxidil	acute aortic dissection, unable to control BP, Hypertension	Essential hypertension	Cardiovascular system
15/07/2009	Declined application		levothyroxine (Synthroid)	Hypothyroidism		Hormone preps-systemic excl contraceptive hormones
15/07/2009	Declined application		fentanyl	chronic pain	Chronic pain	Nervous system
15/07/2009	Declined application		etoricoxib	Behcets Disease	Arthropathy in Behcet's syndrome	Nervous system
15/07/2009	Declined application		mycophenolate	Systemic lupus erythematosis SLE	Systemic lupus erythematosus	Oncology agents and immunosuppressants
15/07/2009	Approved renewal of authority		cubison tube feed	Epidermolysis Bullosa	Epidermolysis bullosa	Special foods
15/07/2009	Declined application		macrogol (Movial Half Powder)	spina bifida	Spina bifida	Alimentary tract and metabolism
15/07/2009	Approved renewal of authority		growth hormone	hypoglycaemic seizures, multiple pituitary hormone deficiencies	Hypopituitarism	Hormone preps-systemic excl contraceptive hormones
15/07/2009	Declined application		bromhexine hydrochloride (bisolvon)	COPD, respiratory failure	Respiratory failure	Respiratory system and allergies
15/07/2009	Approved renewal of		sirolimus	lymphangiomyomatosis	Lymphangiomyomatosis	Oncology agents and immunosuppressants

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	authority					
15/07/2009	Declined application		olopatadine (Patanol)	bilateral ectropion, nasolacrimal obstruction		Sensory organs
15/07/2009	Approved renewal of authority		magnesium	renal tubular acidosis/Gitelman's syndrome	Familial hypokalaemia-hypomagnesaemia	Alimentary tract and metabolism
15/07/2009	Approved initial application		cysteamine	Cystinosis	Cystinosis	Sensory organs
14/07/2009	Declined renewal	auto	paroxetine (Aropax)	Anxiety and Depression	Chronic depression	Nervous system
13/07/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
10/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	trying to become pregnant		Hormone preps-systemic excl contraceptive hormones
10/07/2009	Automatic renewal of authority		propylthiouracil	severe itch with carbimazole		Hormone preps-systemic excl contraceptive hormones
10/07/2009	Automatic renewal of authority		propylthiouracil	intolerance of carbimazole		Hormone preps-systemic excl contraceptive hormones
10/07/2009	Automatic approval of initial application		ethambutol			Infections - agents for systemic use
10/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	intra pregnacy graves disease cbz associated with aplasia		Hormone preps-systemic excl contraceptive hormones
9/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	Currently pregnant		Hormone preps-systemic excl contraceptive hormones
9/07/2009	Declined application		ketotifen	eosinophilic gastroenteritis		Alimentary tract and metabolism
9/07/2009	Declined application		valganciclovir	CMV, uveitis		Infections - agents for systemic use
8/07/2009	Automatic		propylthioura	allergic rash with		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	approval of initial application		cil (Propylthiouracil)	carbimazole		
7/07/2009	Automatic renewal of authority		liothyronine	Primary Hypothyroidism		Hormone preps-systemic excl contraceptive hormones
7/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
7/07/2009	Automatic approval of initial application		propylthiouracil	pregnancy		Hormone preps-systemic excl contraceptive hormones
7/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	cough recurred with retrial		Hormone preps-systemic excl contraceptive hormones
7/07/2009	Declined application	auto	omeprazole (Losec)	gastro-esophageal reflux		Alimentary tract and metabolism
7/07/2009	Declined renewal	auto	paroxetine (Aropax)	moderate severe depression	Moderate major depression	Nervous system
3/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
3/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
1/07/2009	Approved initial application		diazoxide	hyperinsulinaemia, hypoglycaemia		Hormone preps-systemic excl contraceptive hormones
1/07/2009	Declined application	Transferred to Hospital EC	ciprofloxacin (Cipflox)	Cystic fibrosis, pseudomonas aeruginosa	Pseudomonas aeruginosa	Infections - agents for systemic use
1/07/2009	Declined application	Leave as HEC	phenindione	adverse reaction to warfarin, DVT	Deep venous thrombosis	Blood and blood forming organs
1/07/2009	Declined application	Transferred to Hospital EC	mycophenolate	juvenile rheumatoid arthritis, lupus nephritis, SLE/RA		Oncology agents and immunosuppressants

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
				overlap		
1/07/2009	Declined application		losartan	Hypertension		Cardiovascular system
1/07/2009	Declined application		celecoxib	Osteoarthritis		Nervous system
1/07/2009	Approved renewal of authority		tacrolimus ointment	mucosal lichen planus, unresponsive to conventional treatment	Lichen planus	Oncology agents and immunosuppressants
1/07/2009	Declined application		levonorgestrel (Mirena)			Hormone preps-systemic excl contraceptive hormones
1/07/2009	Approved renewal of authority		anakinra	adult onset Stills disease	Adult onset Still's disease	Musculo-skeletal system
1/07/2009	Approved renewal of authority		interferon gamma-1b	Chronic granulomatous disease	Chronic granulomatous disease	Infections - agents for systemic use
1/07/2009	Approved renewal of authority		enoxaparin	allergy to warfarin, prosthetic aortic heart valve	Mechanical prosthetic aortic valve replacement	Cardiovascular system
1/07/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic rash on funded carbimazole		Hormone preps-systemic excl contraceptive hormones
1/07/2009	Approved renewal of authority		cyclosporin	cytophagic panniculitis	Cytophagic histiocytic panniculitis	Oncology agents and immunosuppressants
1/07/2009	Approved renewal of authority		diazoxide liquid	hyperinsulinism	Hyperinsulinism	Hormone preps-systemic excl contraceptive hormones
30/06/2009	Automatic approval of initial application		liothyronine (Tertroxin)	hypothyroid, poor response to thyroxine		Hormone preps-systemic excl contraceptive hormones
29/06/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
29/06/2009	Automatic renewal of authority		prednisolone sodium phosphate	oral lichen planus		Dermatologicals

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
			(Redipred)			
26/06/2009	Automatic renewal of authority		liothyronine (Tertroxin)	hypothyroidism		Hormone preps-systemic excl contraceptive hormones
23/06/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	pregnancy		Hormone preps-systemic excl contraceptive hormones
23/06/2009	Awaiting decision on renewal, information received	Received additional information	interferon gamma-1b	Chronic granulomatous disease	Chronic granulomatous disease	Infections - agents for systemic use
23/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
23/06/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	intorerance of carbimazole		Hormone preps-systemic excl contraceptive hormones
23/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic reaction		Hormone preps-systemic excl contraceptive hormones
23/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	abnormal liver function tests		Hormone preps-systemic excl contraceptive hormones
23/06/2009	Approved renewal of authority		desmopressin tablets	central diabetes insipidus, Langerhanns histiocytosis, central diabetes insipidus, Langerhans histiocytosis, unresponsive to spray	Secondary diabetes insipidus	Hormone preps-systemic excl contraceptive hormones
23/06/2009	Approved renewal of authority	auto	thioridazine	Schizophrenia - Chronic,Paranoid Type, stable	Chronic paranoid schizophrenia	Nervous system
23/06/2009	Automatic		propylthioura	thyroid disease		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	renewal of authority		cil (Propylthiouracil)			
22/06/2009	Declined application	auto	paroxetine (Aropax)	Depression		Nervous system
22/06/2009	Automatic approval of initial application	auto	ethambutol	mycobacterium avium intracellulae complex		Infections - agents for systemic use
22/06/2009	Automatic renewal of authority		phenoxybenzamine (Dibenyline)	prostatitis	Prostatitis	Alimentary tract and metabolism
22/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	intorerance of carbimazole		Hormone preps-systemic excl contraceptive hormones
22/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
22/06/2009	Approved renewal of authority		lorenzo's oil (glycerol trierucate, glycerol trioleate)	adrenoleukodystrophy	Adrenoleukodystrophy	Alimentary tract and metabolism
22/06/2009	Declined application		erythropoietin (Eprex)	anaemia, Jehovah's Witness, myelofibrosis	Aplastic anemia due to chronic disease	Blood and blood forming organs
22/06/2009	Declined application		omeprazole (Losec)	Gastro oesophageal reflux		Alimentary tract and metabolism
19/06/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	Intolerant to Carbimazole		Hormone preps-systemic excl contraceptive hormones
19/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	thyroid disease		Hormone preps-systemic excl contraceptive hormones
19/06/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	Hepatitis		Hormone preps-systemic excl contraceptive hormones
19/06/2009	Automatic		propylthioura	rash and headache		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	approval of initial application		cil (Propylthiouracil)			
19/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
19/06/2009	Automatic approval of initial application		albendazole	Hydatid cyst of the liver		Infections - agents for systemic use
18/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	intending to become pregnant		Hormone preps-systemic excl contraceptive hormones
17/06/2009	Declined application		demeclocycline	hyponatraemia		Alimentary tract and metabolism
17/06/2009	Declined application		montelukast	Asthma		Respiratory system and allergies
17/06/2009	Declined application		levetiracetam	spinal myoclonus		Nervous system
17/06/2009	Declined application		omeprazole (Losec)	Gastro oesophageal reflux		Alimentary tract and metabolism
17/06/2009	Approved renewal of authority		etanercept	relapsing polychondritis	Relapsing polychondritis	Oncology agents and immunosuppressants
17/06/2009	Declined application		voriconazole	candida parapsilosis, Fungal endophthalmitis		Infections - agents for systemic use
17/06/2009	Approved renewal of authority		filgrastim (Neupogen)	profound neutropenia, type 1 glycogen storage disease	Metabolic neutropenia	Blood and blood forming organs
17/06/2009	Declined application		moxifloxacin	Bronchiectasis, multidrug resistant strep pneumoniae		Infections - agents for systemic use
17/06/2009	Approved renewal of authority		lorenzo's oil (glycerol trierucate, glycerol trioleate)	adrenoleukodystrophy	Adrenoleukodystrophy	Alimentary tract and metabolism
17/06/2009	Declined		omeprazole	Gastro		Alimentary tract and metabolism

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	application		(Losec)	oesophageal reflux		
17/06/2009	Approved renewal of authority		cholesterol powder	Smith-Lemli-Optiz	Smith-Lemli-Opitz syndrome	Alimentary tract and metabolism
17/06/2009	Declined application		deferasirox (Exjade)	Haemachromatosis, iron overload, intolerant of desferrioxamine, pyruvate kinase deficiency		Blood and blood forming organs
17/06/2009	Awaiting more information on application		diazoxide	hyperinsulinaemia, hypoglycaemia		Hormone preps-systemic excl contraceptive hormones
17/06/2009	Declined application	Leave as HEC	ursodeoxycholic acid	peroxisomal biogenesis defect	Disorder of peroxisomal function	Alimentary tract and metabolism
17/06/2009	Declined application		chlordiazepoxide	familial mediterranean fever		Nervous system
17/06/2009	Approved initial application		idebenone	Friedreich's Ataxia	Friedreich's ataxia	Alimentary tract and metabolism
17/06/2009	Declined application	Transferred to Hospital EC	cyclosporin	pyoderma gangrenosum		Oncology agents and immunosuppressants
16/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
16/06/2009	Awaiting more information on application		celecoxib	neck injury		Nervous system
16/06/2009	Awaiting more information on application		omeprazole (Losec)	Gastro oesophageal reflux		Alimentary tract and metabolism
16/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour, unusual psychiatric event - also depressed & school reported big problems with him	Attention deficit hyperactivity disorder	Nervous system
15/06/2009	Awaiting more	Letter, but	enoxaparin	allergy to warfarin,		Blood and blood forming organs

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	information on application	no actual application		recurrent venous thrombosis, thrombo-embolism, allergy to warfarin		
15/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	breastfeeding		Hormone preps-systemic excl contraceptive hormones
12/06/2009	Automatic renewal of authority		propylthiouracil	allergic reaction		Hormone preps-systemic excl contraceptive hormones
12/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour		Nervous system
11/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
11/06/2009	Declined application		methylphenidate (Ritalin)	ADHD		Nervous system
10/06/2009	Automatic approval of initial application		liothyronine (Tertroxin)	intolerant of various thryroxine preparations		Hormone preps-systemic excl contraceptive hormones
10/06/2009	Automatic approval of initial application		phenoxybenzamine	benign prostate hypertrophy	Benign prostatic hyperplasia	Hormone preps-systemic excl contraceptive hormones
10/06/2009	Automatic approval of initial application		albendazole	Hydatid cyst of the liver		Infections - agents for systemic use
10/06/2009	Declined application		methylphenidate (Ritalin)			Nervous system
10/06/2009	Declined application	Meets Special Authority criteria	tiotropium	COAD		Respiratory system and allergies
10/06/2009	Automatic renewal of authority		pimozide	Gilles de la Tourette syndrome	Gilles de la Tourette's syndrome	Nervous system
10/06/2009	Automatic renewal of		propylthiouracil	reaction to carbimazole		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	authority					
10/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
9/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour		Nervous system
8/06/2009	Automatic approval of initial application		liothyronine (Tertroxin)	Hyopthyroidism, inadaquate response to Thyroxine		Hormone preps-systemic excl contraceptive hormones
8/06/2009	Automatic approval of initial application		prednisolone sodium phosphate (Redipred)	Asthma		Dermatologicals
5/06/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	pregnancy		Hormone preps-systemic excl contraceptive hormones
5/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	pregnancy		Hormone preps-systemic excl contraceptive hormones
5/06/2009	Automatic renewal of authority		propylthiouracil (Propylthiouracil)	pregnant and plans to breast feed		Hormone preps-systemic excl contraceptive hormones
4/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour, unusual psychiatric event - hallucinating on Rubifen	Attention deficit hyperactivity disorder	Nervous system
4/06/2009	Approved renewal of authority		cyclosporin	chronic active hepatitis, non-responsive to 6 mercaptopurine	Chronic active hepatitis	Oncology agents and immunosuppressants
4/06/2009	Declined application		sertraline	Depression		Nervous system
4/06/2009	Approved initial application		cyclosporin	dermatomyositis		Oncology agents and immunosuppressants

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
3/06/2009	Declined application		valganciclovir	CMV, uveitis		Infections - agents for systemic use
3/06/2009	Declined application		fentanyl (Durogesic)	chronic pain, oesophageal stricture	Pain in limb	Nervous system
3/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour		Nervous system
3/06/2009	Declined application		modafinil	Multiple Sclerosis		Nervous system
3/06/2009	Approved renewal of authority		desmopressin (Minirin)	adverse reaction to generic, hypophysectomy	Hypophysectomy	Hormone preps-systemic excl contraceptive hormones
3/06/2009	Approved renewal of authority		cyclosporin	ITP	Idiopathic thrombocytopenic purpura	Oncology agents and immunosuppressants
3/06/2009	Approved renewal of authority		cholesterol powder	Smith Lemli Opitz syndrome	Smith-Lemli-Opitz syndrome	Alimentary tract and metabolism
3/06/2009	Declined application		olopatadine (Patanol)	bilateral ectropion, nasolacrimal obstruction		Sensory organs
3/06/2009	Declined application		growth hormone	hypopituitarism		Hormone preps-systemic excl contraceptive hormones
3/06/2009	Declined application		mycophenolate	lupus nephritis, Systemic lupus erythematosis SLE		Oncology agents and immunosuppressants
2/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
2/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
2/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	unusual psychiatric event - very unsettled, behavioural changes at school & home	Attention deficit hyperactivity disorder	Nervous system
2/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
2/06/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
2/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	allergic reaction		Hormone preps-systemic excl contraceptive hormones
2/06/2009	Awaiting more information on application		levetiracetam	spinal myoclonus		Nervous system
2/06/2009	Automatic approval of initial application		propylthiouracil (Propylthiouracil)	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
29/05/2009	Approved renewal of authority		captopril	hypertension	Hypertensive disorder	Cardiovascular system
29/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
28/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
28/05/2009	Approved initial application		l-dopa (Simemet)	PTPS	6-pyruvoyltetrahydropterin synthase	Alimentary tract and metabolism
28/05/2009	Approved initial application		5-hydroxytrytophan	PTPS	6-pyruvoyltetrahydropterin synthase	Alimentary tract and metabolism
28/05/2009	Automatic renewal of authority	auto	enalapril maleate (renitec)	hypertension, side effects on generic		Cardiovascular system
28/05/2009	Automatic approval of initial application		propylthiouracil	allergic rash on funded carbimazole		Hormone preps-systemic excl contraceptive hormones
28/05/2009	Automatic approval of initial application		propylthiouracil	allergic reaction ongoing Graves disease		Hormone preps-systemic excl contraceptive hormones
28/05/2009	Automatic approval of		propylthiouracil	pregnancy		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	initial application					
27/05/2009	Automatic renewal of authority		propylthiouracil	allergic reaction to carbimazole		Hormone preps-systemic excl contraceptive hormones
27/05/2009	Automatic approval of initial application		propylthiouracil	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
26/05/2009	Declined application	auto	amlodipine (Norvasc)	headache with alternate, Hypertension		Cardiovascular system
25/05/2009	Declined renewal		paroxetine (Aropax)	Depression	Chronic depression	Nervous system
25/05/2009	Automatic renewal of authority		propylthiouracil	anaphyllaxisis		Hormone preps-systemic excl contraceptive hormones
22/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour		Nervous system
22/05/2009	Automatic approval of initial application		propylthiouracil	urticarial rash		Hormone preps-systemic excl contraceptive hormones
22/05/2009	Automatic approval of initial application		propylthiouracil	Is sexully active and might get pregnant		Hormone preps-systemic excl contraceptive hormones
22/05/2009	Automatic renewal of authority		propylthiouracil	rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
21/05/2009	Declined application		buprenorphine			Nervous system
21/05/2009	Declined application		n-acetyl cysteine	idiopathic pulmonary fibrosis	Idiopathic fibrosing alveolitis, chronic form	Respiratory system and allergies
21/05/2009	Declined application		tacrolimus	oral lichen planus	Oral lichen planus	Dermatologicals
21/05/2009	Declined application		cubitan	epidermylosis bullosa dystrophica	Dystrophic epidermolysis bullosa	Special foods
21/05/2009	Declined		sildenafil	coronary artery	Coronary artery	Cardiovascular system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	application			vasospasm	spasm	
21/05/2009	Declined application		rosiglitazone (Avandia)	Type II Diabetes		Alimentary tract and metabolism
21/05/2009	Automatic approval of initial application		propylthiouracil	severe skin reaction		Hormone preps-systemic excl contraceptive hormones
21/05/2009	Automatic approval of initial application		propylthiouracil	skin reaction extensive rash		Hormone preps-systemic excl contraceptive hormones
21/05/2009	Declined application		enoxaparin	thrombophlebitis	Thrombophlebitis	Blood and blood forming organs
21/05/2009	Declined application		methylphenidate (Concerta)	idiopathic day time hypersomnolence		Nervous system
20/05/2009	Approved renewal of authority		potassium citrate liquid	distal renal tubular acidosis	Distal renal tubular acidosis	Alimentary tract and metabolism
20/05/2009	Automatic approval of initial application		propylthiouracil	allergic reaction		Hormone preps-systemic excl contraceptive hormones
20/05/2009	Awaiting more information on application		biotin	pyruvate dehydrogenase deficiency		Alimentary tract and metabolism
20/05/2009	Declined application		pramipexole	Depression, Parkinson's Disease	Parkinson's disease	Nervous system
20/05/2009	Awaiting more information on application		co-enzyme q10			Alimentary tract and metabolism
20/05/2009	Approved renewal of authority		diazoxide liquid	hyperammonaemia, Hyperinsulinism, inborn error of metabolism	Hyperinsulinism	Alimentary tract and metabolism
20/05/2009	Automatic renewal of authority		propylthiouracil	trying to become pregnant		Hormone preps-systemic excl contraceptive hormones
20/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
20/05/2009	Approved renewal of authority		interferon gamma-1b	Chronic granulomatous disease	Chronic granulomatous disease	Infections - agents for systemic use
20/05/2009	Approved renewal of authority		deferasirox	complications of desferrioxamine infusion, iron overload due to blood transfusion, pyruvate kinase deficiency	Desferrioxamine adverse reaction	Blood and blood forming organs
20/05/2009	Approved renewal of authority		cetrimide in hibitane shampoo	ichthyosis	Cutaneous syndrome with ichthyosis	Dermatologicals
20/05/2009	Approved renewal of authority		itraconazole	Disseminated Coccidiomycosis	Disseminated coccidioidomycosis	Infections - agents for systemic use
20/05/2009	Approved renewal of authority		3,4 diaminopyridine	Lambert Eaton myasthenic syndrome	Eaton-Lambert syndrome	Nervous system
20/05/2009	Approved renewal of authority		carmellose sodium eye drops (Celluvisc)	keratopathy, severe dry eye syndrome, Sjogrens syndrome	Tear film insufficiency	Sensory organs
19/05/2009	Automatic approval of initial application		liothyronine (Tertroxin)	total thyroidectomy for thyroid cancer, pre radioactive iodine		Hormone preps-systemic excl contraceptive hormones
19/05/2009	Declined application		atorvastatin (Lipitor)	hyperlidaemia, HIV		Blood and blood forming organs
18/05/2009	Automatic renewal of authority		pimozide	Bipolar Disorder, chronic depression	Bipolar disorder	Nervous system
18/05/2009	Declined application		methylphenidate (Ritalin)			Nervous system
18/05/2009	Automatic renewal of authority		pimozide	Schizoaffective disorder	Schizoaffective disorder	Nervous system
15/05/2009	Automatic renewal of authority		phenoxybenzamine (Dibenzyline)	pheochromocytoma	Pheochromocytoma	Cardiovascular system
15/05/2009	Automatic approval of		propylthiouracil	pregancy		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	initial application					
15/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
15/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	narcolepsy	Narcolepsy	Nervous system
15/05/2009	Automatic renewal of authority		propylthiouracil	preconception and breastfeeding		Hormone preps-systemic excl contraceptive hormones
15/05/2009	Automatic renewal of authority		propylthiouracil	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
15/05/2009	Automatic approval of initial application		propylthiouracil	Skin rash with Carbimazole		Hormone preps-systemic excl contraceptive hormones
14/05/2009	Automatic renewal of authority		prednisolone sodium phosphate oral liquid (Redipred)	Mucous membrane pemphigus		Dermatologicals
14/05/2009	Automatic renewal of authority		propylthiouracil	breast feeding		Hormone preps-systemic excl contraceptive hormones
14/05/2009	Automatic renewal of authority		propylthiouracil	pregnancy		Hormone preps-systemic excl contraceptive hormones
14/05/2009	Deferred decision on application		amikacin	mycobacterium tuberculosis	Infection due to Mycobacterium tuberculosis	Infections - agents for systemic use
14/05/2009	Deferred decision on application		moxifloxacin	drug resistant tuberculosis, mycobacterium tuberculosis	Infection due to Mycobacterium tuberculosis	Infections - agents for systemic use
14/05/2009	Deferred decision on application		para-amino salicylic acid	mycobacterium tuberculosis	Infection due to Mycobacterium tuberculosis	Infections - agents for systemic use
14/05/2009	Deferred decision on application		prothionamide (Peteha)	mycobacterium tuberculosis	Infection due to Mycobacterium tuberculosis	Infections - agents for systemic use

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
14/05/2009	Automatic approval of initial application		phenoxybenzamine	benign prostate hypertrophy		Cardiovascular system
13/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
13/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
13/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
12/05/2009	Automatic approval of initial application		prednisolone (Redipred)	Crohns Disease, buccal granulomatosis		Dermatologicals
12/05/2009	Automatic approval of initial application		propylthiouracil	deterating control on full doses of carbaimazole		Hormone preps-systemic excl contraceptive hormones
11/05/2009	Automatic renewal of authority		propylthiouracil	diarrhoea		Hormone preps-systemic excl contraceptive hormones
8/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
8/05/2009	Automatic renewal of authority		liothyronine	Intolerant of thyroxine		Hormone preps-systemic excl contraceptive hormones
8/05/2009	Automatic renewal of authority		propylthiouracil	Severe rash with Carbimazole		Hormone preps-systemic excl contraceptive hormones
8/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour		Nervous system
7/05/2009	Automatic approval of initial application		liothyronine	Post thyroidectomy thyroid cancer awaiting radioactive iodine		Hormone preps-systemic excl contraceptive hormones
7/05/2009	Automatic renewal of		methylphenidate (Ritalin)	aggressive or threatening	Attention deficit hyperactivity	Nervous system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	authority			behaviour	disorder	
7/05/2009	Approved initial application	Approved as Delegated Authority	tacrolimus	Paraneoplastic Pemphigus	Pemphigus paraneoplastica	Oncology agents and immunosuppressants
7/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour, irritability, dizziness	Attention deficit hyperactivity disorder	Nervous system
7/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
7/05/2009	Automatic approval of initial application		propylthiouracil	Gastrointestinal side effects with Carbimazole		Hormone preps-systemic excl contraceptive hormones
7/05/2009	Declined application	Transferred to Hospital EC	amphotericin (Fungizone)	Allergic bronchopulmonary aspergillosis, Cystic fibrosis	Aspergillosis	Infections - agents for systemic use
7/05/2009	Automatic renewal of authority		propylthiouracil	rash		Hormone preps-systemic excl contraceptive hormones
7/05/2009	Declined application		candesartan	Hypertension		Cardiovascular system
6/05/2009	Declined application		omeprazole (Losec)	GORD		Alimentary tract and metabolism
6/05/2009	Approved renewal of authority		mycophenolate	desquamative interstitial pneumonia	Dyspnea	Oncology agents and immunosuppressants
6/05/2009	Declined application		omega 3, vitamin b complex	hydrocephaly		Alimentary tract and metabolism
6/05/2009	Approved renewal of authority		desmopressin tablets	Panhypopituitarism, Panhypopituitarism with ADH, Gh, ACTH,TSH deficiency	Panhypopituitarism	Hormone preps-systemic excl contraceptive hormones
6/05/2009	Declined application	Transferred to Hospital	idebenone	Friedreich's Ataxia	Friedreich's ataxia	Alimentary tract and metabolism

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
		EC				
6/05/2009	Approved initial application		insulin (Apidra)	diabetes Type 1	Diabetes mellitus type 1	Alimentary tract and metabolism
6/05/2009	Declined application		insulin aspart (insulin & diluent) (Novorapid)	insulin dependant diabetes mellitus, sensitive to insulin	Diabetes mellitus type 1	Hormone preps-systemic excl contraceptive hormones
6/05/2009	Declined application		insulin detemir	diabetes	Diabetes mellitus type 1	Hormone preps-systemic excl contraceptive hormones
6/05/2009	Approved initial application		cisapride	abdominal pain		Nervous system
6/05/2009	Declined application		mycophenolate (Roche)	mixed connective tissue disorder		Nervous system
6/05/2009	Declined application		tramadol	chronic pain control		Nervous system
6/05/2009	Declined application		sertraline (Zoloft)	Depression		Nervous system
6/05/2009	Declined application		ondansetron	diabetes mellitus, gastroparesis, Renal Transplant, retinopathy	Gastroparesis syndrome	Nervous system
6/05/2009	Approved initial application		cyanocobalamin	pernicious anaemia	Pernicious anemia	Alimentary tract and metabolism
6/05/2009	Approved renewal of authority		tacrolimus ointment	Crohns disease, orofacial granulomatosis	Orofacial granulomatosis	Dermatologicals
5/05/2009	Declined application	auto	paroxetine (Aropax)	chronic depression		Nervous system
5/05/2009	Automatic approval of initial application		propylthiouracil	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
5/05/2009	Automatic approval of initial application		propylthiouracil	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
5/05/2009	Automatic renewal of authority		propylthiouracil	rash and pregnancy		Hormone preps-systemic excl contraceptive hormones
5/05/2009	Automatic renewal of authority		propylthiouracil	pregnancy		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
5/05/2009	Automatic approval of initial application		propylthiouracil	sore throat and nausea		Hormone preps-systemic excl contraceptive hormones
4/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour		Nervous system
4/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour, unusual psychiatric event - headaches, feeling 'crazy', tremor, sleepy	Attention deficit hyperactivity disorder	Nervous system
4/05/2009	Declined application		methylphenidate (Ritalin SR)			Nervous system
1/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
1/05/2009	Automatic renewal of authority		methylphenidate (Ritalin)	ADHD, aggressive or threatening behaviour		Nervous system
1/05/2009	Automatic approval of initial application		propylthiouracil	patient is pregnant		Hormone preps-systemic excl contraceptive hormones
1/05/2009	Automatic approval of initial application		propylthiouracil	pregnancy		Hormone preps-systemic excl contraceptive hormones
1/05/2009	Automatic renewal of authority		propylthiouracil	adverse effect - asthralgia, cracked skin		Hormone preps-systemic excl contraceptive hormones
1/05/2009	Automatic approval of initial application		propylthiouracil	impending pregnancy		Hormone preps-systemic excl contraceptive hormones
30/04/2009	Declined application		paroxetine (Aropax)	bipolar disorder, depression		Nervous system
30/04/2009	Approved renewal of	auto	thioridazine	Behavioural problems,	Problem behaviour	Nervous system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	authority			intellectual disability		
30/04/2009	Automatic renewal of authority		pimozide	Schizophrenia	Schizophrenia	Nervous system
30/04/2009	Declined application	auto	paroxetine (Aropax)	anxiety/panic disorder		Nervous system
30/04/2009	Approved initial application	Approved as Delegated Authority	interferon gamma-1b (Imukin)	chronic granulomatous disease	Chronic granulomatous disease	Infections - agents for systemic use
29/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour, unusual psychiatric event - suicidal thoughts	Attention deficit hyperactivity disorder	Nervous system
29/04/2009	Approved initial application		moxifloxacin	mycobacterium tuberculosis	Infection due to Mycobacterium tuberculosis	Infections - agents for systemic use
29/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour		Nervous system
29/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
28/04/2009	Automatic renewal of authority		pimozide	delusional disorder	Delusional disorder	Nervous system
27/04/2009	Automatic renewal of authority		propylthiouracil	pregnancy		Hormone preps-systemic excl contraceptive hormones
27/04/2009	Approved renewal of authority		imiglucerase (cerezyme)	Gaucher's disease type III	Subacute neuronopathic Gaucher's disease	Alimentary tract and metabolism
24/04/2009	Automatic approval of initial application		propylthiouracil			Hormone preps-systemic excl contraceptive hormones
24/04/2009	Automatic renewal of authority		propylthiouracil	Migratory polyarthritis		Hormone preps-systemic excl contraceptive hormones
24/04/2009	Automatic		propylthioura	Currently		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	approval of initial application		cil	breastfeeding		
24/04/2009	Automatic approval of initial application		propylthiouracil	rash on carbimazole		Hormone preps-systemic excl contraceptive hormones
24/04/2009	Automatic renewal of authority		propylthiouracil	breastfeeding		Hormone preps-systemic excl contraceptive hormones
23/04/2009	Approved renewal of authority		xlys low try maxamaid	glutaric aciduria type 1	Glutaric aciduria, type 1	Alimentary tract and metabolism
23/04/2009	Approved renewal of authority		xlys low try maxamaid	glutaric aciduria type 1	Glutaric aciduria, type 1	Special foods
23/04/2009	Approved renewal of authority		xlys low try maxamaid	glutaric aciduria type 1	Glutaric aciduria, type 1	Alimentary tract and metabolism
23/04/2009	Approved renewal of authority		cyclosporin	autoimmune hepatitis, intolerant of azathioprine, 6-mercaptopurine	Autoimmune hepatitis	Oncology agents and immunosuppressants
23/04/2009	Approved renewal of authority		mycophenolate	hepatitis due to azathioprine	Bilateral sequential single lung transplant	Oncology agents and immunosuppressants
23/04/2009	Approved initial application		montelukast	mastocytosis, urticaria pigmentosa	Urticaria pigmentosa	Respiratory system and allergies
22/04/2009	Approved renewal of authority		l-carnitine	Medium Chain Acyl coA dehydrogenase deficency	Medium-chain acyl-coenzyme A dehydrogenase deficiency	Alimentary tract and metabolism
22/04/2009	Approved renewal of authority		trientine	Wilson's disease	Wilson's disease	Musculo-skeletal system
22/04/2009	Approved initial application		sodium benzoate	encephalopathy, hyperammonaemia	Hyperammonemic encephalopathy	Alimentary tract and metabolism
22/04/2009	Approved renewal of authority		etanercept (enbrel)	Inflammatory Treatment to the Aorta, Systemic Lupus	Secondary aortitis	Musculo-skeletal system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
				Erythematosis (SLE) with aortitis & aortic valve replacement		
22/04/2009	Approved renewal of authority		whole thyroid (porcine)	intolerance of thyroxine, total thyroidectomy	Thyroxine adverse reaction	Hormone preps-systemic excl contraceptive hormones
22/04/2009	Declined application		omeprazole (Losec)	Gastro oesophageal reflux		Alimentary tract and metabolism
22/04/2009	Approved initial application		acitretin	Harlequin ichthyosis	Harlequin ichthyosis	Alimentary tract and metabolism
22/04/2009	Declined application		tacrolimus	oral lichen planus	Oral lichen planus	Dermatologicals
22/04/2009	Declined application		thyroxine (Synthroid)	Hypothyroidism		Hormone preps-systemic excl contraceptive hormones
21/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
21/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
21/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
21/04/2009	Automatic approval of initial application		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
21/04/2009	Automatic renewal of authority		propylthiouracil	Allergic to Carbimazole, Hyperthyroidism		Hormone preps-systemic excl contraceptive hormones
20/04/2009	Automatic approval of initial application		propylthiouracil	trying to become pregnant		Hormone preps-systemic excl contraceptive hormones
20/04/2009	Automatic approval of initial application		propylthiouracil	hair loss, planning pregnancy		Hormone preps-systemic excl contraceptive hormones
20/04/2009	Automatic renewal of authority		propylthiouracil	pre pregnancy		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
16/04/2009	Declined application	auto	paroxetine (Aropax)	Anxiety and Depression		Nervous system
16/04/2009	Approved renewal of authority	auto	pimozide (Orap)	Schizophrenia	Schizophrenia	Nervous system
16/04/2009	Declined application		methylphenidate (Ritalin)			Nervous system
16/04/2009	Declined renewal	auto	paroxetine (Aropax)	depression and anxiety, side effects with loxamine		Nervous system
15/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour, unusual psychiatric event - sleep latency, mood 'low', cried frequently, appetite poor causing weight loss, moderately severe tics limted dosage	Attention deficit hyperactivity disorder	Nervous system
15/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
15/04/2009	Automatic renewal of authority		propylthiouracil	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
15/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
15/04/2009	Automatic approval of initial application		propylthiouracil	allergic reaction to carbimazole		Hormone preps-systemic excl contraceptive hormones
15/04/2009	Automatic approval of initial application		propylthiouracil	rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
15/04/2009	Automatic approval of initial		propylthiouracil	itchy rash with carbimazole		Hormone preps-systemic excl contraceptive hormones

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	application					
15/04/2009	Automatic approval of initial application		propylthiouracil	rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
15/04/2009	Automatic approval of initial application		propylthiouracil	allergic skin reaction to carbimazole		Hormone preps-systemic excl contraceptive hormones
15/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
15/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
15/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour - more unsettled, off task, has needed to come out of class at times	Attention deficit hyperactivity disorder	Nervous system
15/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
15/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
9/04/2009	Declined application		paroxetine (Aropax)	Depression		Nervous system
9/04/2009	Declined application		sertraline	Depression	Severe depression	Nervous system
9/04/2009	Approved renewal of authority		mifepristone	Benign metastasising leiomyoma	Benign metastasizing leiomyoma of uterus	Oncology agents and immunosuppressants
9/04/2009	Approved renewal of authority		trientine	Wilson's disease	Wilson's disease	Musculo-skeletal system
9/04/2009	Declined application		urea cream 10% (Nutraplus)	chronic pityriasis rubra pilaris	Pityriasis rubra pilaris	Dermatologicals

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
9/04/2009	Declined application		urea cream 10% (Nutraplus)	congenital bullous ichthyosiform erythroderma	Dominant congenital ichthyosiform erythroderma	Dermatologicals
9/04/2009	Declined application		paroxetine (Aropax)	Major Depression, Multiple Sclerosis	Severe depression	Nervous system
9/04/2009	Declined renewal		paroxetine (Aropax)	Depression		Nervous system
9/04/2009	Declined application		mirtazapine	Major Depression	Severe depression	Nervous system
9/04/2009	Approved initial application		albendazole	Hydatid cyst of the liver		Infections - agents for systemic use
9/04/2009	Declined application		cinacalcet	end stage renal failure, Tertiary hyperparathyroidism, TPN	Tertiary hyperparathyroidism	Hormone preps-systemic excl contraceptive hormones
8/04/2009	Automatic approval of initial application		propylthiouracil	breastfeeding		Hormone preps-systemic excl contraceptive hormones
8/04/2009	Declined application		natalizumab (Tysabri)			Nervous system
8/04/2009	Declined application		paroxetine (Aropax)	Major Depression	Severe depression	Nervous system
8/04/2009	Declined renewal	auto	paroxetine (Aropax)	Depression		Nervous system
8/04/2009	Declined application		omeprazole (Losec)	Reflux oesophagitis and erosive gastritis	Gastro-esophageal reflux disease with esophagitis	Alimentary tract and metabolism
8/04/2009	Declined application		insulin (Apidra)	diabetes Type 1	Diabetes mellitus type 1	Alimentary tract and metabolism
8/04/2009	Declined application		mycophenolate	bronchiolitis obliterans, inflammatory bowel disease	Inflammatory bowel disease	Oncology agents and immunosuppressants
8/04/2009	Declined application		timolol (Minims 0.5%)	glaucoma	Glaucoma	Sensory organs
8/04/2009	Declined renewal		paroxetine	loss of effect with loxamine, premenstrual syndorme	Premenstrual tension syndrome	Infections - agents for systemic use

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
7/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
7/04/2009	Automatic approval of initial application		propylthiouracil	unresponsive to carbimazole		Hormone preps-systemic excl contraceptive hormones
7/04/2009	Automatic renewal of authority		propylthiouracil	pregnant		Hormone preps-systemic excl contraceptive hormones
7/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
7/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
7/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
6/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
6/04/2009	Awaiting more information for renewal currently inactive		whole thyroid (porcine)	intolerance of thyroxine, total thyroidectomy	Thyroxine adverse reaction	Hormone preps-systemic excl contraceptive hormones
6/04/2009	Automatic approval of initial application		propylthiouracil	allergic skin reaction to carbimazole		Hormone preps-systemic excl contraceptive hormones
6/04/2009	Automatic approval of initial application		propylthiouracil	derranged liver function on carbimazole		Hormone preps-systemic excl contraceptive hormones
3/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
3/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
3/04/2009	Automatic		methylphenid	aggressive or	Attention deficit	Nervous system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
	renewal of authority		ate (Ritalin)	threatening behaviour	hyperactivity disorder	
3/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
3/04/2009	Declined application		timolol (Timoptol)	allergy to preservative, Dry eye disease, glaucoma	Glaucoma	Sensory organs
3/04/2009	Automatic approval of initial application		methylphenidate (Ritalin)			Nervous system
3/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
2/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour		Nervous system
2/04/2009	Automatic approval of initial application		methylphenidate (Ritalin)			Nervous system
1/04/2009	Declined application		candesartan	Hypertension		Cardiovascular system
1/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
1/04/2009	Approved initial application	Approved as Delegated Authority	imatinib mesylate	systemic mastocytosis (indolent)	Indolent systemic mastocytosis	Oncology agents and immunosuppressants
1/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
1/04/2009	Automatic approval of initial application		propylthiouracil	Itch with Carbimazole		Hormone preps-systemic excl contraceptive hormones
1/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system

Event date	Event	Reason	Drug	Categories	SNOMED primary indication	Therapeutic group
1/04/2009	Automatic approval of initial application		propylthiouracil	dermatological reaction to carbimazole		Hormone preps-systemic excl contraceptive hormones
1/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
1/04/2009	Automatic renewal of authority		propylthiouracil	severe allergic reaction to carbizamole		Hormone preps-systemic excl contraceptive hormones
1/04/2009	Automatic renewal of authority		methylphenidate (Ritalin)	aggressive or threatening behaviour	Attention deficit hyperactivity disorder	Nervous system
1/04/2009	Automatic approval of initial application		propylthiouracil	acute memory loss & confusion on low dose		Hormone preps-systemic excl contraceptive hormones
1/04/2009	Automatic renewal of authority		propylthiouracil	breastfeeding		Hormone preps-systemic excl contraceptive hormones
1/04/2009	Automatic renewal of authority		propylthiouracil	trying to become pregnant		Hormone preps-systemic excl contraceptive hormones
1/04/2009	Automatic renewal of authority		propylthiouracil	allergic rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
1/04/2009	Automatic approval of initial application		propylthiouracil	itchy rash with carbimazole		Hormone preps-systemic excl contraceptive hormones
1/04/2009	Automatic approval of initial application		propylthiouracil	joint pains, nausea with carbimazole		Hormone preps-systemic excl contraceptive hormones

Appendix 9: Analysis of Material Received Under the Official information Act Requests.

Table 1: Analysis of Material Released by PHARMAC under the Official Information Act 1982 First Request

Doc. No.	Data	Source/Type.	Points to Note	Comments
1	Sep. 2002	PHARMAC EC Committee Annual Report to PHARMAC Board	1. Report notes that the 'better' the clinical and scientific information provided in the EC application the better the 'judgment' the panel can apply. 2.The table of drugs which have been approved under EC, 2% of the number of applicants expended 28% of the total costs. 3. Page 10 refers to terminally ill patients. The comment is made *"it would seem illogical to spend significant amounts of money on cancer treatments in order to give a few more years of life to a patient and then expect them to spend their final days in extreme discomfort".* The last statement on the page refers to the avoidance of treating people who are "*not truly terminally ill patients"*.	There is no sense that any information other than clinical or scientific analysis is of any value. It is clear that EC is about rare conditions but it is also about high cost medicines. These are value laden decisions. The Panel did not explain why they came to these conclusions about who to treat and why or give reference to the moral principles which lie behind these judgments.
2	August 1999	Minutes from the Board Meeting of the Health Funding Authority, Personal Health Purchasing Board	The document notes that this is the first time a full-time employee Case Manager has been approved to manage Special High Cost Medicines Budget and EC Budget. Business rules and referral protocols for referrals between HFA regions are established.	This formally establishes EC as part of PHARMAC and sets up the business rules under which EC will function within PHARMAC
3	August 1999	Email Addressee and Addressor withheld	This email points out (presumably to PHARMAC) that the requirement of a Cost-utility Analysis for drugs over $30,000 per year could place a considerable burden on PHARMAC.	PHARMAC are concerned that $30,000 per QALY could place budget constraints on PHARMAC under the new EC business rules.
4	July 1999	Draft specifications –Case Management Services, Health Funding Authority	Much of this document is withheld. The document sets out the definition of EC, the service users, access, service components, processes, skills and experience required, equipment, support services, settings, service levels, linkages, exclusions, quality requirements, reporting requirements.	It is important to note that the EC policy was being 'purchased' by the HFA under the purchaser-provider split. This contract between the HFA and PHARMAC was in preparation for the NZPHDA 2000 which was going through Parliament in 1999.
5	July 1999	Glossary of Terms-HFA	Establishes the EC Budget within the HFA.	
6	unknown	Email Addressee and Addressor	Looks like this is from the Ministry of Health complaining that there has been poor	There was poor communication between the HFA, Ministry of Health and PHARMAC setting up EC under PHARMAC.

Doc. No.	Data	Source/Type.	Points to Note	Comments
		withheld	communication between them and the HFA and PHARMAC re setting up the EC budget.	
7	August 1999	Letter from Therapeutic Group Manager, PHARMAC to the HFA.	Commenting on the Referral Protocols and Business Rules being set up for EC. PHARMAC are pointing out that the rarity requirement of EC "dominates". They are saying that this should be one of the criteria but not the sole criteria. .	PHARMAC are signaling that the assessment of 'exceptional' is a multidimensional decision making process and not simply limited to the criteria of 'rarity' which dominates.
8	June 2004	Record of EC Panel Meeting	1.Dr. Mel Briesman noted that the EC process was better now because there is more medical input. 2. The panel noted that there were many medical conditions which were more frequent than 10 in numbers which failed the EC criteria. If the number was increased to 15 or 20 annually, this would have a significant impact on the budget. 3. Evidence of benefit was often limited to a 'trial' of N=1.The EC recognises that the trial could simply be the doctor or the patient saying the schedule treatment was 'unsuccessful'.	There is a heavy reliance on opinion of medical personnel about EC applications qualifying under the criteria. There is no input from other sources to determine the fairness of decisions. If more budget for EC was available then more patients would qualify. Primarily, EC is a budget constrainer not a method of providing care to patients whose needs fall outside the schedules. The criterion requires the patient is to have tried a medication from the existing schedule is undermined by this process..
9	August 1999	Paper-HFA Specifications – Case Management Services, Health Funding Authority	Final Protocols and Business Rules for PHARMAC to operate EC.	
10	July 1999	Email Addressee and Addressor withheld	The correspondent makes several criticisms of the criterion for 'exceptional' The fact that that a medicine has not been effective does not make the case for 'exceptional circumstances'. The correspondent raises the following questions.. What is the definition of a drug that 'does not work'? Does this include side effects? How severe? What is efficacy? Is it 75% effective or 50% effective or even 25% effective? How long does 'success' in treatment last? There is no definition of the 'trial' or 'trial period'.	This person is suggesting that the definition for 'exceptional' is meaningless and gives the EC Panel license to include or exclude as they wish.
11	November 1998	HFA Exceptional Circumstances Policy Review	1.This paper is saying that 'exceptional circumstances' means rare conditions. Applications are assessed on health needs, suitability of treatment, cost-benefit and cost-	This is the first time that the patient's income has been introduced into the funding criteria. There is no explanation as to why a person's income should be a factor in the granting of an 'exceptional circumstances' subsidy. The patient must be eligible for a Community Service Card[1] and

[1] A Community Services Card was issued to persons who were a single person with an annual income of $22,366 or less, a person who is married or living in a de facto or civil union relationship with an income of less than $35,420, a family of 2 earning $42,760 or less, family of 3 earning $51,788 or less up to a family of 6 earning $73,849 or less. The Community

Doc. No.	Data	Source/Type.	Points to Note	Comments
			effectiveness, availability of funds and patient's income. 2. All applications are considered by Dr. Mel Briesman on behalf of all HFA's in NZ.	receiving the maximum benefit levels from the NZ Income Support Service before the subsidy can be approved. Presumably a person not on a Community services Cards cannot get 'Exceptional Circumstances' subsidy. This system is dependant on the judgments of one Doctor for the whole county.
12	November 1998	Email to Annemarie Blanchy of the HFA from Addressor withheld	The correspondent states " if Mel approved this one we may as well throw reference pricing out the window!"	The correspondent is dissatisfied that Dr. Briesman has allowed an EC claim. The comment shows the sensitivity of PHARMAC to being undermined by the decision of the Medical Advisor.
13	July 2002	Letter from PHARMAC to DHBNZ.re a teleconference on EC	The criteria for approving EC have changed. The PHARMAC Board has lowered the threshold from $30,000 per QALY to $15,000 per QALY in the cost-utility analysis. A CUA is now required on all applications of $30,000 per annum or greater.	This was a significant shift tightening the application process in the CUA model.
14	June 2002	Minutes from PHARMAC Board Meeting	A change in the EC criteria. If the QALY is less than or equal to $15,000 per year the EC Panel can approve the application. If the cost of the QALY is greater than $15,000 per QALY the decision to fund is passed to the DHB and all other DHBs to agree or not. If all DHBs agree that application can then be approved.	This gives applicants an 'out' of the QALY calculation. If all DHBs (accessed through the DHBNZ Primary Health Group) agree to an EC claim then the application will succeed. How would one DHB assess the affordability of another DHB to meet the costs of a Hospital EC claim?
15	June 2002	Memo to the PHARMAC Board Meeting	Same paper as above.	
16	June 2002	Memo to the PHARMAC Board Meeting Exceptional Circumstances Cost-Benefit Criterion	The paper set out to clarify how the EC Panel will use the cost –benefit criteria to provide certainty to the Panel on how to administer the criteria.	The only consultation conducted by PHARMAC on how the EC Panel will use the cost-benefit analysis was the DHBNZ group which provided feedback. There was no other public consultation.
17	September 2002	Letter from PHARMAC to Julian Inch of DHBNZ	Letter confirms the PHARMAC policy that medicines being considered of $30,000 annual cost require a cost-utility analysis to be done for the EC Panel. If the QALY is below $15,000 the Panel can approve the application. The letter notes the possible pressure on the EC budget.	

Services Card was also issued to people who were on an Unemployment Benefit, Sickness Benefit, Domestic Purposes Benefit, Widow's Benefit, Independent Youth Benefit, Invalid's Benefit, Emergency Benefit, Veteran's Pension. The CSC could be used to reduce the cost.

Doc. No.	Data	Source/Type.	Points to Note	Comments
18	Unknown	Email from the EC Panel to the Project Manager, PHARMAC	The Panel has the first application for EC under the new policy and do not know how to proceed and are asking PHARMAC for guidance. The cost of the drug is estimated to be $250,000 per year and the Panel note the total budget for EC is $2.5m.	The Panel is in a quandary about approving one application for 10% of the whole EC budget. The Panel is anticipating the CUA is above $15,000. There is no mention of how this patient's quality of life is valued or the gain to the person, family or community against this $250,000 cost of the treatment.
19	Unknown	Notes for teleconference with DHBNZ Primary Health Group regarding Exceptional Circumstances applications with a CUA of greater than $15,000	The EC Panel received an application of a patient who otherwise fits the EC criteria for iloprost[2] with a cost possible to exceed $200,000 for one year treatment. Several issues are raised which criticize the CUA model. The paper points out that the cost per QALY is 'an indicative only' reference. The paper finally says despite the flaws in the process "In these circumstances, spending would appear to offer good value for money".	The statement 'good value for money' is based on the CUA process which is accepted as indicative only. Again there is no value appreciation of the patient's actual life. Good value for whom? PHARMAC or the Patient? This is a statement made in the absence of an agreed set of values on which to base such determinations.
20	January 2002	Relationship Agreement between District Health Boards and PHARMAC	EC is referred to is subject to a legislative mandate of PHARMAC to assume responsibility for EC as from 1 October 2001. The funding for this comes from the national pharmaceutical budget and set at $2.5m. PHARMAC is required to report to DHBS on an annual basis relating to EC. The service budget to manage EC by PHARMAC is set at $130,000.	Start up date for EC with PHARMAC under the new legislation is 1 October 2001.
21	June 2001	Sara Fredricks, Ministry of Health to PHARMAC	The Pediatric Society have requested that a special panel for EC applications be established for children's applications under EC.	There is dissatisfaction among the doctors in relation to the EC Panel's understanding the issues related to children's EC applications.
22	June 2001	Memo to PHARMAC Board of Directors Meeting.	The major paper setting up EC Panel, the budget, reporting standards and date of commencement 1 October 2001. PHARMAC staff were required under the law to consult on this policy. The consultation in this case was only with the medical profession, pharmacy profession and the pharmaceutical companies. For example the submission from Starship Hospital stated that PHARMAC should be transparent in relation to the EC budget. This means publication of an EC annual report by PHARMAC and this report should be made available to the Ministry of Health and the Pediatric Society. This would ensure "buy in" from the community. This is an accusation of a closed nature of the thinking between the medical professions and PHARMAC. There appears little room for the public to influence EC and PHARMAC by debating principles which underpin the EC	Section 48(e) of the NZ PHDA 2000 requires PHARMAC to consult widely in relation to establishing regulation and processes. PHARMAC did not consult with the public over the criteria for the EC policy.

[2] Iloprost is a drug used in the treatment of Pulmonary Hypertension, which is high blood pressure in the arteries which supply blood to the lungs.

Doc. No.	Data	Source/Type.	Points to Note	Comments
			processes. For example the principles of fairness, equality, openness. The Manawatu doctors submitted that it was most important that doctors are compensated for assisting patients with filling in the EC forms. They also commented that the EC criteria should be more flexible, sensible and realistic. There is no discussion about what this means.	
23	May 2001	Letter from PHARMAC to whom it may concern.	Request for comment on shifting the EC funding from the MoH to PHARMAC policy. There is no indication where this letter was distributed.	The Board papers indicate that only medical profession, pharmacy profession and the pharmaceutical companies responded.
24	May 2001	Letter from PHARMAC to Whanganui DHB, Wanganui	Request for comment on shifting the EC funding from the MoH to PHARMAC policy. Presumably this letter went to all the 21 DHBs asking for comment.	
25	May 2001	Letter from PHARMAC to CEOs of DHBs	Request for comment on shifting the EC funding from the MoH to PHARMAC policy. Presumably this letter went to all the 21 DHB CEOs.	
26	Unknown	Paper, information on Structure for EC Management	This paper sets out the case for a full time administrator, an analyst and a Panel of Clinicians to administer the EC policy.	This paper identifies that one individual doctor and two part-time people had been making all the EC decisions. The is discussion that this needs to be improved because the 'growth in approvals. PHARMAC believe that as regards EC 'better' means fewer approvals. There is also stress on the staff coming from patients and doctors "who may not agree with the decisions they have made". This is very interesting because it means that for 6 years EC was seen as largely administrative. EC is very judgment and principles based decision making and this had been done in the absence of any guidance other than the 3 criteria which are very open to interpretation.
27	June 2001	Memorandum to PHARMAC Board of Directors	Outlines issues relating to EC for the Board to consider.	Identifies the three criteria to be met for EC. Rarity, reaction to alternative treatment, and unusual combination of circumstances. In 1998 the patient's income was a factor however in 2001 this seems to be dropped. There are other matters to be taken into account but this information is withheld in this document.
28	April 1997	To PHARMAC from Central RHA	Recommendations to PHARMAC from Central RHA on EC Policy. This document says that the Central RHA made a decision not to funds a person under the EC policy. The RHA's decision was challenged by a lobby group under s 157 of the Crimes Act and Chapter 29 of the Magna Carta. Chapter 29 of the Magna Carta originally stated that "No freeman is to be taken or imprisoned or disseised of his free tenement or of his liberties or free customs, or outlawed or exiled or in any way ruined, nor will we go against such a man or send against him save by lawful judgment of his peers	These two items shows that Section 157 of the Crimes Act refers to a duty to avoid omissions dangerous to life. "Every one who undertakes to do any act the omission to do which is or may be dangerous to life is under legal duty to do that act, and is criminally responsible for the consequences of omitting without lawful excuse to discharge that duty". Section 157 of the Crimes Act and Article 29 of the Magna Carta were appealed to in the case to establish that PHARMAC's EC policy was depriving the claimant of life by an act of omission by PHARMAC and hence PHARMAC was 'putting to death" without the due process of law. The outcome of the challenge is withheld by PHARMAC under the OIA.

Doc. No.	Data	Source/Type.	Points to Note	Comments
			or by the law of the land. To no one will we sell or deny or delay right or justice." This was amended in 1354 by Edward III to read as follows: ". . . no man of what estate or condition that he be, shall be put out of land or tenement, nor taken, nor imprisoned, nor disinherited, nor put to death, without being brought in answer by due process of law." (A. Clark, October 2, 2008).	
29	October 1996	Memorandum from the Ministry of Health to the Members of the Pharmaceutical Policy Group	Paper indicating that PHARMAC intends to publish information on EC policy in the December copy of the Pharmaceutical Schedule. A fax is also included from Dr. Winston McKean, Southern Region Health Authority. McKean indicates that the wording of the policy document is incorrect.	EC claimant's income is considered in the policy. Firstly, the persons income and circumstances have been assessed and the person is eligible for a Community Services Card, the person is receiving the maximum NZISS benefit available to them OR "…that it is otherwise unreasonable to expect them to pay". This is the first time this last condition has appeared. How are the administrators to assess if something is 'reasonable'? There are no guiding principles to explain reasonable.
30	Unknown	1995/96 RHA	Published Funding Agreement published by the Regional Health Authority in relation to Access to Pharmaceuticals	
31	July 1996	Memorandum from PHARMAC staff to PHARMAC Directors	Paper on Publishing Exceptional Circumstances Processes to be published in the Pharmaceutical Schedule.	
32	July 1996	Memorandum from Medical Director of PHARMAC to unknown, Possibly the Ministry of Health	This is the formal notification of the additions to be included in the Pharmaceutical Schedule	
33	November 1995	Memorandum from PHARMAC to RHA's Clinical Managers reporting on EC	Report on the previous years applications from the 4 RHA's for EC applications. The RHA is identified, the name of the drug, the patients condition the yearly cost, the outcome of the application and comments.	PHARMAC has advanced the idea of patient's ability to pay by explaining what is reasonable for the patient to pay. "the reasons why it is unreasonable to expect the individual to meet the costs of this therapy". Note inability to pay for treatment does not by itself constitute exceptional circumstances". This means that if there are not other grounds for EC then the inability to pay for a medication is not grounds for EC.
34	Unknown	Unknown	A paper on the criteria on EC in relation to the 1995/96 RHA Funding Agreement.	This appears to be a policy paper between PHARMAC and the Ministry of Health.
35	August 1994	Letter from Hon J Shipley, Minister of Health to Dr. Winston McKean, GM Health Needs and Policy, Southern Regional	The minister approves the EC criteria. She draws attention to the wording and ensures that the policy is correctly worded. The responsibility for paying for EC is not on the Crown Health Enterprises but rests with the Regional Funding Authority.	The Minister is approving what has been in operation for many months.

Doc. No.	Data	Source/Type.	Points to Note	Comments
		Health Authority		
36	November 1995	PHARMAC to the Clinical Directors of the RHs.	Paper on Publishing Exceptional Circumstances Processes to be published in the Pharmaceutical Schedule calling for comment on the paper.	Sent to the 4 RHAs
37	July 1995	Letter from Dr. Mel Briesman on behalf of PHARMAC to Dr. J Hedley, Physician at Wairau Hospital.	Dr. Briesman is asking for advice on how he should deal with the applications relating to Dnase[3] He is suggesting a different set of criteria than was agreed. He is trying to get greater clarity around other signs and symptoms in Cystic Fibrosis.	Dr. Briesman is suggesting using the NZ Guidelines Group advice on the treatment of Cystic Fibrosis.
38	Unknown	Unknown	The document refers to 'The Committee' and complainants are made at the lack of medical consultation and publicity about the policy.	The PHARMAC staff record that the policy is part of the Funding Agreements with the RHA's and the policy has not been signed off by the Minister.
39	September 1995	Letter from Graham Drury, General Manager Northern Regional Health Authority	The letter points out the Section in the Funding Agreement which was changed by the Minister which says that people who otherwise cannot reasonably meet the costs of drugs which are subject to an EC claim may qualify.	The GM points out that there is no clarification or direction about what this phrase means. There is no definition of 'unreasonable' and no stated principles which reasonableness can be based on.
40	September 1995	Fax from Central RHA to unknown addressee	Making suggestions for EC policy. Suggested changing the wording slightly.	
41	July 1995	Paper from PHARMAC to PTAC Members on the criteria for EC	This paper discusses 3 options for assessing the patient's ability to pay for EC medications. One is to charge the patients a proportion of their income for the medication, the second is a single base payment of $300 and the third is the same payment rules should apply to EC medicines as apply to all other pharmaceuticals.	This paper discusses the patient's ability to pay for the medication in terms of their ability to meet charges imposed by the government. It does not address the issue of their ability to pay the total cost of the medication. The proposed systems are for patients who claim EC and do not have a Community Services Card. This paper discusses the philosophical basis for the health service. It says that the state cannot provide everything that may be needed there for the state should only provide a 'core' of services. The paper then states that EC is outside the core, and therefore should be paid for by the individual and not the State. The paper states that an 'income barrier is quite appropriate'. The paper puts the alternate view that the health service should meet the needs of the patients and decisions should be based on need, therefore EC should not be related to a patient's income. The idea of the core of health services excludes public provision of services to those whose

[3] Dnase is a drug used in the treatment of cystic Fibrosis and disorders to DNA structure in some other genetic disorders.

Doc. No.	Data	Source/Type.	Points to Note	Comments
				illnesses fall outside this definition. This offends the principles of fairness and equity.
42	July 2005	Notes on Teleconference on EC attendees PHARMAC staff and RHA staff..	The paper discusses the proposed raft of EC Criteria which has been approved by the joint RHA CEO's and is awaiting the Minister's approval. The discussion is also about Dnase and the extraordinary high cost. There is also a schedule of EC applications and the costs.	The Committee is struggling with the Dnase applications because they have the potential to consume a great proportion of the EC total budget. Discussion is around how effective the treatment actually is.
43	July 1996	Minutes from PHARMAC Board Meeting	The Board agrees to publish the EC Criteria in the nest Pharmaceutical Schedule.	
44	June 1995	Letter from Medical Director of PHARMAC to Clinical Service Managers RHAs.	An EC application has been referred to the Chair of PTAC for comment. The Chair is unequivocal and not helpful in making a decision either way.	
45	June 2005	Paper from CEOs of RHA approving the EC Criteria	This paper is the RHAs CEOs decision to charge EC non-Community Service Card holders the same charges as other patients pay on Community Schedule and Special Schedule prescriptions. In this paper the PHARMAC staff argue against this	The decision avoids the discussion about the 'core' and the values around it. This decision is likely to involve PHARMAC (the RHA, the Taxpayer) in substantial more cost.
46	April 1995	Teleconference between RHA Joint Personal Health Service Managers and PHARMAC	Item 5 in the notes raises the situation where the prescribing length of time needed by the patient is an 'exceptional circumstance'.	This raises the issue of exceptional types of treatment as related to a non-exceptional type of treatment. For example the case given in the teleconference was for a long er than 10 days supply of nystatin[4]. This issue has not been dealt with before and the policy (in 1995) does not cover this eventuality.
47	Unknown	1995/96 RHA	Published Funding Agreement published by the Regional Health Authority in relation to Access to Pharmaceuticals	Identical paper to item 30
48	March 1995	PHARMAC to Dr. Mel Breisman, Southern RHA	Comment on income criteria for EC. This paper proposes the 'Core' idea and why EC falls outside the core.	This is identical script to that which was given to the PHARMAC Board and PTAC in item 41. There is an important statement which is made by the Medical Director of PHARMAC[5].The statement says "…there will always be a disparity between the decisions made on the basis of benefit to the population and those that would be made if we could prioritize on the basis of individual benefit. A consequence of defining a core on the basis of population benefit is that there will be individuals who gain access to services despite minimal health gain and there will be individuals who do not gain access to services that provide significant health gain to them (because the average gain across the group is too small to justify inclusion in the core).
49	March 1995	Paper and Fax of record of teleconference from Dr. Mel	Identical paper as in Item 30.	No discussion from Dr. Briesman he is simply sending on the comments which were generated by PHARMAC.

[4] Nystatin is an antifungal drug with is effective against specific fungi and yeasts. These fungal infections can be resistant to treatment and often require long duration of action of the drug to eradicate the infection.

[5] I recognise the handwriting of Dr. Win Bennett the Medical Director of PHARMAC on this paper sand the Fax Header which sent this document to Dr. Briesman.

Doc. No.	Data	Source/Type.	Points to Note	Comments
		Briesman to RHA Joint Personal Health Service Managers		
50	December 1994	Notes from teleconference from Dr. Mel Briesman to RHA Joint Personal Health Service Managers	Summary of items discussed. Decided to seek Ministry of Health's comments re financial 'affordability' issue.	
51	December 1994	Notes from teleconference from Dr. Mel Briesman to RHA Joint Personal Health Service Managers	Dr. Briesman issues a paper outlining reasonable costs in other areas of health care.	This paper introduces the figure of $300 which is reasonable to pay for EC medicines by people who do not have a Community Services Card. The arguments are firstly, pharmaceuticals up to $300 are considered reasonable then a high user card is issued. Then the costs of GP visits are considered. A GP visit @$30 once a month amounts to $360, finally Patients are charged $50 per day for inpatient care up to a maximum of $500. He thinks $300 is reasonable.
52	December 1994	Notes from teleconference from Dr. Mel Briesman to RHA Joint Personal Health Service Managers	Summary of items discussed	
53	November 1994	Dr. Mel Briesman to PHARMAC	This is a list of questions that Dr. Briesman is posing to PHARMAC about the criteria for approval, the approval system and the reporting to the PHARMAC Board.	
54	November 1994	Dr. Mel Briesman to PHARMAC	Same document as above repeated.	
55	October 1994	Dr.Win Beasley, Medical Director of PHARMAC to PHARMAC's Pharmaceutical Policy Group.	1.This paper discusses the obligation on the RHAs to provide for EC. He raises two problems with the policy group.	This paper calls for PHARMAC to take over the joint RHA responsibility for EC. The paper calls for a set of business rules to be established and discusses the 'affordability' question. There is the suggestion made that Social Welfare might do an income assessment on each EC applicant. The issue is PHARMAC should keep the discussion in house until the

Doc. No.	Data	Source/Type.	Points to Note	Comments
			2.There is a recommendation to delay public discussion of the mechanism until the policy is developed	policy is developed.
56	October 1994	Dr.Win Beasley, Medical Director of PHARMAC to to RHA Joint Personal Health Service Managers	Agenda for teleconference and adjoining papers for the meeting.	This paper speaks of the PHARMAC Board rejecting the advice from the PHARMAC staff on the setting up of an EC section within PHARMAC. The Board wants the staff to explore a single person doing the job or an agency within PHARMAC. They called for another paper from the PHARMAC staff.
57	September 1994	Northern RHA Personal Health Manager to RHA Joint Personal Health Service Managers	The paper is mostly withheld by PHARMAC however there is record of discussion about EC and setting up an agency within PHARMAC.	First suggestion of a Medical Officer from Southern Regional Health Authority, ie Dr. Mel Briesman.
58	September 1994	Northern RHA Personal Health Manager to RHA Joint Personal Health Service Managers	This one page identifies that the PHARMAC Board rejected the idea of EC being handled by one agency largely because of funding difficulties.	
59	September 1994	Paper from PHARMAC staff to the PHARMAC Directors Board Meeting.	This is the paper that was rejected by the Board. The suggestion was made that a transitional arrangement be made to get va single agency going and that it should be the SRHA. The policy was to be kept quiet in the mean time and finally the Board decreed that there be another paper from staff reviewing the Funding Agreement.	Important that a 'no' decision was made, that the EC process was started in the meantime while the Board made the decision and that the policy formation process was to be kept away from the public.
60	September 1994	Northern RHA Personal Health Manager to RHA Joint Personal Health Service Managers	A discussion paper from Health Benefits Limited (HBL). HBL was the section of the Ministry of Health which handled the payments of all the health benefits and kept the records. Such as all pharmaceutical benefit claims made by pharmacies, all radiological benefits made by hospital radiology departments and private radiologists, the General Medical Services Benefit which was claimed by General Practitioners each time they saw a patient etc. HBL recommended many practical processes to keep track of decisions and funding generated by the decisions.	This was formative information to PHARMAC in establishing the EC policy.
61	August 1994	Dr.Win Beasley, Medical Director of PHARMAC to to RHA Joint Personal Health Service Managers	A draft paper suggesting the establishment of EC policy.	This paper went to the Pharmaceutical Policy Group which was a committee of the PHARMAC Board.
62	Unknown	Unknown, probably	A further Paper titled Subsidisation of	This paper talks about the abolition of Section 99 special Authority in

Doc. No.	Data	Source/Type.	Points to Note	Comments
		PHARMAC staff.	Pharmaceuticals in Exceptional Circumstances.	December 1993 and the establishment of the Community Pharmaceutical Schedule. The need for a policy on EC is discussed.
63	Unknown	Unknown, probably PHARMAC staff.	A paper outlining the Exceptional Circumstances Approval Process.	
64	June 1994	from Fran McGrath of the Ministry of Health to RHA Joint Personal Health Service	Suggested procedure for the RHAs to follow when considering applications for pharmaceutical subsidy for individual patients.	These are the rules as they were applied by the Ministry of Health. Fran McGrath introduces the notion of Exceptional Circumstances and outlines the policy the Ministry of Health use. She suggests that PHARMAC Pharmaceutical Policy Group takes up the paper and develops its own policy settings for “Exceptional Circumstances”.

Table 2: Analysis of Material Released by the Minister of Health under the Official Information Act 1982

Doc. No.	Date/File No.	Source/ Type.	Points to Note	Comments relating to Exceptional Circumstances
65	April 2002/ HR20033686	Briefing paper by MoH for the Minister re a meeting between Minister and representatives from Pfizer Pharmaceutical Group	Pfizer representatives complained that they are paying very high rebates to PHARMAC as a result of Lipitor contract, They were concerned that PHARMAC was not listing new medicines, particularly Pfizer medicines. Pfizer raised concerns about PHAMRAC not funding their Alzheimer's drug on the schedule and complained that PHARMAC was not consulting with companies or the public effectively.	PHARMAC stated to the Minister that they had instigated the recommendations of the Caygill-Lexchin Report specifically they had established a Consumer Consultation Committee to enable PHARMAC to consult better with the public.
66	January 2005/ HR20057461	PHARMAC Meeting with Associate Minister of Health Hon. Pete Hodgson	A briefing paper to Hodgson on the functions of PHARMAC, key issues relating to the pharmaceutical companies, reference pricing and the pharmaceutical budget.	None
67	November 2005 HR20059324	Briefing paper by MoH for Minister before a meeting with PHARMAC.	Minister was advised that PHARMAC is likely to under-spend its Community Pharmaceutical Budget. The Minister was advised that work on the Medicines Strategy scoping exercise (required by United Future as part of the govt. Coalition Agreement) is underway by the MoH. PHARMAC wishes to discuss its Annual Review 04-05 and he was advised of increases in costs related to Cancer treatment drugs. Finally he was advised that PHARMAC is asking for an increased operating budget.	This raises the question if the Community Pharmaceutical budget is under spent, why is not the 'Exceptional Circumstances' budget not increased in that year?
68	June 2006 HR20060934	Briefing paper by MoH for Minister before a meeting with PHARMAC.	Minister was briefed on medicines procurement policy. The paper discusses the development of the Medicines Strategy and the possible impact on PHARMAC. The Minister was advised CEO being seconded to Dept. Prime Minister and Cabinet.	In this briefing PHARMAC justifies the 'at least one drug per drug category' policy by saying that patients have access to drugs free albeit a limited supply where as in other countries where there is a greater range of drugs available through public funding, however the patients are required to make greater co-payments, Responding to the claim that PHARMAC's funding decisions unfairly discriminate against patients with rare diseases and in need of high-cost medicines PHARMAC claims that the three 'Exceptional Circumstances' schemes manage this unfairness. They go on to tell the Minister that rare means one case in 10 nationally.
69	July 2006 HR20061448	Briefing paper by MoH for Minister before a meeting with PHARMAC	A briefing to the Minister advising that PHARMAC seek an amendment to the NZ Public Health and Disability Act (2000) to increase the delegation powers provided to the Medical Director of PHARMAC to approve 'Exceptional Circumstances' claims between $15,000 and $30,000. The MoH support the recommendation.	PHARMAC reasons for providing the delegated authority to the Medical Director to approve 'Exceptional Circumstances' claims between $15,000 and $30,000 is that the Chief Executive has the delegated authority however the decisions are of a clinical nature and in the absence of the CE or the Deputy CE decisions are unnecessarily delayed.
70	Sept. 2006 HR20061448 (BRO6 331)	Briefing paper by MoH for Minister before a meeting with	The industry representatives wanted the government to introduce an external appeals process for PHARMAC's funding decisions as is in place in Australia, Canada and the United Kingdom, The MoH advised the Minister that all PHARMAC's decisions are subject to	The reasons for declining an appeals process were that the MoH (and PHARMAC) believed the current system was adequate, an appeals process would be expensive and an external appeal authority might not have the

Doc. No.	Date/File No.	Source/ Type.	Points to Note	Comments relating to Exceptional Circumstances
		pharmaceutical industry representatives	Judicial Review and the establishing an appeals process was not necessary	competence to judge such matters and it may undermine PHARMAC's budget by making decisions PHARMAC could not afford to fund. For example blowing out the 'Exceptional Circumstances' budget on one or two overturned decisions. This would cause PHARMAC and/or the DHBs to go into deficit.
71	Sept. 2006 HR20061545	A briefing paper by MoH for Minister on the NZ Pharmaceutical Industry Taskforce Interim Paper.	The Pharmaceutical Industry Taskforce provided the Minister with an interim report on issues relating to NZ's access to pharmaceuticals being reduced because of PHARMAC's procurement policies. The MoH also provided the Minister with independent review of the Taskforce's interim report.	The MoH in consultation with PHARMAC reject the opinions of the Taskforce and refute all their arguments. The independent report provided by BERL[6] to the Minister on the Taskforce's interim report refutes the Taskforces analysis on the basis that few (if any) facts are presented to support their criticisms and claims that the current system is unfair and not providing NZ people with adequate access to medicines. The comment on the recommendations made by the Taskforce in the BERL report is partially withheld under the Terms of the OIA.
72	Oct. 2006 HR20062154	A briefing paper by MoH for Minister on the NZ Pharmaceutical Industry complaint about PHARMAC.	The Pharmaceutical industry raised the complaint the PHARMAC's decision-making processes used to determine which medicines will be subsidised are not transparent. The MoH stated that improving transparency of the decision-making process will need to be balanced against concerns to protect commercially sensitive information about PHARMAC's negotiating positions.	The MoH acknowledge that the potential to increase public transparency of PHARMAC's schedule and 'Exceptional Circumstances' decision making process could be beneficial to both the industry and the public. However the Ministry warns that transparent about the process does not mean acceptance of the decisions would be any greater by either the industry in relation to funding on the schedule or 'Exceptional Circumstances; decisions. An example of the publicly available material on the cost benefit analysis and the decision relating to Gleevec, an expensive drug used in the treatment of acute myeloid leukemia is available. Interestingly the prices paid for the drug by PHARMAC is withheld under terms and conditions of the OIA.
73	August 2007 HR20071442	Briefing to the Minster on a meeting with PHARMAC re the Medicines Strategy; PHARMAC, PTAC and DHB relationships.	MoH advise Minister that many of the submissions received in the NZ Medicines Strategy Consultation process are about PHARMAC's relationship management and refining its processes.	The Ministry recommends the Minister ask PHARMAC to increase DHB expertise on the PHARMAC Board, improve the process of appointing PTAC members, allow pharmaceutical companies to meet with them before the Board considers funding applications, expanding the role of the Consumer Advisory Committee and improve reporting through the Statement of Intent to Parliament.
74	Sept. 2007 HR20071752	Briefing to the Minster on a meeting with PHARMAC re an update on the Medicines Strategy;	The MoH provides the Minister with an update on the submissions received on the proposed Medicine Strategy, possible areas of improvement and advice on community pharmaceuticals budget, and the proposed Therapeutic Products and Medicines Bill. ,	Again PHARMAC transparency is raised in the submissions on The Medicine Strategy. The MoH claim that the stakeholders are laboring under many 'misconceptions' about PHARMACs funding processes, particularly in relation to 'Exceptional Circumstances'. The complaints about PHARMAC style of consultation and limited engagement with stakeholders are substantial. The

[6] Business and Economic research Limited Ref# 4034

Doc. No.	Date/File No.	Source/ Type.	Points to Note	Comments relating to Exceptional Circumstances
				MoH make suggestions to improve the relationships between the public, the industry and PHARMAC.
75	Sept. 2007 HR 20071792	Briefing to the Minster on a meeting with PHARMAC on enhancing PHARMAC's stakeholder engagement with industry and the public	The MoH paper advises the Minister on how PHARMAC intend to improve their relationship with the pharmaceutical industry, the general public and a broader range of stakeholders. It discusses PHARMAC's work on a Stakeholder Engagement Strategy as part of the medicines strategy work. Reference is made to the Caygill and Lexchin report in 2000 independent review of PHARMAC's procedures and policies. They recommended an improved relationship with the industry and the public.	PHARMAC outline measures to improve its accountability to the stakeholders. It is suggested by the MoH that this will lead to a greater understanding of the issues which PHARMAC is grappling with, including value for money and the difficulty of providing subsidy under 'Exceptional Circumstance' within a constrained budget.
76	October 2007 HR20071734	Briefing paper to the Minister re structural arrangements for PHARMAC	The DHBs raised with the Minister the issue of PHARMAC's dual roles as procurer of pharmaceuticals on behalf of the DHBs and manager of the community pharmaceutical budget. The MoH discuss the role of PHARMQAC and possible alternative structures for PHARMAC under the NZ Public Health and Disability Act 2000. The MoH recommend no change to the current structure because they believe the status quo Crown Agent structure is still the most valid .	The paper recognizes that the structure of Crown Agent means that PHARMAC must "give effect to government policy"and is directly accountable to the Minister and Parliament. The prioritisation decisions made by PHARMAC e.g. rationing under the capped budget, is done at arms length from the Minister. The Crown Agent structure supports decision-making about listing pharmaceuticals on the schedule, pricing and 'Exceptional Circumstances' are the day to day work of PHARMAC not the Minister.

Table 3: Analysis of Material Released by PHARMAC under the Official Information Act 1982 Second Request

Doc. No.	Date/File No.	Source/ Type.	Points to Note Regarding Community Exceptional Circumstances	Comments relating to Exceptional Circumstances
77	22nd February 2006	This is a Memo to the PHARMAC Board of Directors recommending alterations to the Exceptional Circumstances Panel Terms of Reference (ToR).	This is not an instruction from the PHARMAC Board to the Exceptional Circumstances Panel, it is a memo of recommendations to the Board from PHARMAC staff[7]. The Board approved the recommendations and the ToR was consequently sent to the Exceptional Circumstances Panel for enactment. The ToR only relate to the 'Community Exceptional Circumstances' Scheme. The staff recommended that applications above $30,000 per year with a QALY of greater than $15,000 per QALY would be referred to the Exceptional Circumstances Panel for a recommendation to the PHARMAC Board for a final decision. The ToR was changed to include a requiring a Cost-utility Analysis if the application would result in a Net Present Value (discounted rate of 8%) calculation over five years of $52,500 (which equates to an annual cost of $15,000 per year for 5 years). Renewals for 'Exceptional Circumstances' claims will be approved by the Panel without requiring annual approval from the Board	PHARMAC staff wrote the Terms of Reference for the Exceptional Circumstances Panel, there was no direction which came from the Board.[8] The changes to the ToR suggested are entirely administrative and do not relate to the criteria for approval except for the changing of the limits for requiring a CUA to be done and the Net Present Value calculation has been included to long term treatment claims. PHARMAC has introduced a new criterion which takes into account the future costs of 'Exceptional Circumstances' claims before granting approvals.
78	22nd February 2006	Terms of Reference for the Exceptional Circumstances Committee- Part A	The terms of operation of the Community Exceptional Circumstances Committee is described in this document. Under the section 'Records' the Co-ordinator is required to If the application 'clearly' fails to meet any one of the 'Exceptional Circumstances' criteria, then the application can be determined to fail by the Administrator to the Committee. If the application is urgent, the Coordinator may consult with one member of the Committee (the normal Quorum is 3 members) to decide the application. The Committee must decide on applications according to the 'Exceptional Circumstances' criteria. Applicants have the right of appeal. Appeals first require the Committee to provide PHARMAC Board with a report on the application and the Committee then itself considers the appeal. if	The Coordinator makes the first decision about the application proceeding on to be considered by the Committee. The Appeal process is internal until a Medical Consultant is appointed. No person outside the PHARMAC, the Ministry or medical profession is involved in 'Exceptional Circumstances' appeals or complaints against the determinations of the Committee. The Coordinator manages communications between the Committee and the patients and the medical profession.

[7] There is a statement in the Executive Summary of this Board paper saying "The proposal outlines in this Board paper has not been dealt with by the CEO under delegated authority because changes to the terms of reference of the Exceptional Circumstances Panel may be contentious".

[8] Note that PHARMAC made representations to the Minister (October 2007 HR20071734) that under the Crown Entity structure the Board set the policies and procedures for PHARMAC staff to follow. PHARMAC also argued in the McCormack report on high-cost medicines that there was no need for an allocation committee to give advice about prospective contentious prioritisation decisions or to review decisions PHARMAC has already made, because they have a Board who fulfills this function. The example of the Terms of reference for the Exceptional Circumstances Panel being prepared and written by the PHARMAC staff is evidence that the Board is not involved in the formulation of the allocation process regarding 'Exceptional Circumstances'.

			the Committee does not uphold the appeal the case is sent to an Appeal Committee (consisting of one member from PTAC and two others appointed by PHARMAC). The Appeal Committee hears the appeal and their decision is final. PHARMAC may from time to time appoint a Medical Consultant to review the performance of the Committee and report back to PHARMAC..Any report of the Medical Consultant is only to be disclosed to officers of PHARMAC, the Ministry of Health and the Committee. \The Coordinator of the Committee is to manage communications between the Committee and the patients and the medical profession. Complaints about the Committee or their determinations are first considered by the Committee to determine if the complaint is of a serious nature. If so, the Committee refers the matter to the Appeals Committee and provides PHARMAC with a report. The same process applies if PHARMAC or the Ministry receive a complaint about the Committee..If a subsequent complaint is made about the Committee the matter is to be referred to a Medical Consultant who decides on the complaint.	The public are not communicated with.
79	22 February 2006	Criteria For Exceptional Circumstances Funding- Part B	Applications for Community Exceptional Circumstances are considered if the patient is not an in-patient at a public hospital. One of the following criteria must be met; rarity, unusual reaction to an alternative treatment or an unusual combination of circumstances applies. The medicines must be registered as a safe medicine, the dose within the therapeutic range and the application is supported by a medical specialist. The medicine must demonstrate significant clinical benefit or pose less risk than alternatives, the “price of the pharmaceutical sought should be acceptable when assessed on cost benefit grounds and evaluated against other Ministry priorities”. The application must show there is no suitable alternative and alternative treatments have been trialed. Evidence must be included to show that “either the person’s income and circumstances have been assessed and the person is eligible for a community services card, and is already receiving the maximum Work and income benefit available to them or it is otherwise unreasonable to expect them to pay”. All other information provided to the Committee is to be given “due consideration” Approvals are granted for a fixed period.	The rarity criteria means less than 10 patients nationally at an one time. How does the committee know how many people are suffering the csame disease? Is it simply how many people are on the same drugs? This may not be accurate. Cost benefit analysis is done on every application. The price of the medicines applied for must be ‘acceptable’ and evaluated against other Ministry priorities. There is an income test to show the patient is receiving maximum benefits from Work and income, has a Community Services Card or it is otherwise unreasonable to expect them to pay. Information put before the Committee is to be given due consideration.

80	22 February 2006	Reports and Reviews – Part C	The Coordinator is to provide PHARMAC with monthly reports from the Committee. Each year PHARMAC reviews the Committee and discusses the review. The Coordinator provides PHARMAC with relevant records and summaries of monthly reports. The Committee can ask PHARMAC to review or amend the Criteria. The Committee provides PHARMAC with an Annual Report. The Committee and PHARMAC decide on the content and format of the Annual Report.	

Table 4: Analysis of Material Requested by the Department of the Prime Minister and Cabinet (referred to the Minister of Finance and the Minister of Health) under the Official Information Act 1982 Second Request

Doc. No.	Date/File No.	Source/ Type.	Points to Note Regarding Community Exceptional Circumstances	Comments relating to Exceptional Circumstances
78	22nd April 2009 (A20192 30-1.3)	Letter from Maartin Wevers, Chief Executive, Department of Prime Minister and Cabinet	The Department does not hold nor has received any documents which refer to the principles on which PHARMAC is required to make decisions related to 'Exceptional Circumstances' between 2000 and 2008.	There was not political direction to PHARMAC on the establishment of the principles underpinning the 'Exceptional Circumstances' criteria.
79	19th May 2009 (2009012 9)	Letter from Hon Bill English, Minister of Finance.	The Minister advises that no Budget documents were provided to Cabinet by him on the subject of allocations made to PHARMAC for 'Exceptional Circumstances'.	The government did not consider an appropriate level of funding for 'Exceptional Circumstances'.
80	26 May 2009 (No File No.)	Letter from Hon Tony Ryall, Minister of Health	No Cabinet papers were submitted by the Minister which mention PHARMAC's 'Community Exceptional Circumstances' nor any papers which relate to the results of public consultations conducted by PHARMAC between 2000 and 2008.	The Government did not consider any matters relating to 'Exceptional Circumstances' nor any results to public consultations carried out by PHARMAC.