

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics) Name	Indications Studied	Product Labeling	Labeling Changes	BPAA (B)/PREA (P)/Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	NNPS
380.	5/26/2000	Differin Cream	adapalene	Acne vulgaris	<u>Labeling</u>	<ul style="list-style-type: none"> Approved down to 12 years of age 	R	Galderma	NA	
381.	5/22/2000	Optivar	azelastine	Itching associated with Allergic Conjunctivitis	<u>Labeling</u>	<ul style="list-style-type: none"> Safety and effectiveness established down to 3 years 	B	Muro Pharma/Asta Medica	8/11/1999	
382.	4/26/2000	Relenza Rotadisk	zanamivir	Treatment of Influenza A and B	<u>Labeling</u>	<ul style="list-style-type: none"> Approved down to 7 years of age 	R	GlaxoSmithKline	NA	
383.	4/20/2000	Lantus	insulin glargine	Type 1 Diabetes	<u>Labeling</u>	<ul style="list-style-type: none"> Safety and effectiveness established down to 6 years 	B	Aventis	7/12/1999	
384.	4/12/2000	Trivagizole 3 Vaginal Cream	clotrimazole	Vaginal yeast infection	<u>Labeling</u>	<ul style="list-style-type: none"> Approved for OTC use in patients 12 years of age and older 	R	Taro	NA	
385.	4/4/2000	Humalog Injection	insulin lispro	Type 1 diabetes	<u>Labeling</u>	<ul style="list-style-type: none"> Approved for use in the pediatric population; instructions on use of the diluted product in the pediatric population 	R	Lilly	NA	
386.	3/17/2000	Lamisil AT Spray Pump	terbinafine	Jock itch, athlete's foot, ringworm	<u>Labeling</u>	<ul style="list-style-type: none"> Approved for OTC use 	R	Novartis	NA	
387.	2/4/2000	Tri-Nasal Spray	triamcinolone	Allergic rhinitis	<u>Labeling</u>	<ul style="list-style-type: none"> Approved down to 12 years of age 	R	Muro	NA	
388.	1/12/2000	Advil	ibuprofen	Fever, minor aches & pain, cold symptoms	<u>Labeling</u>	<ul style="list-style-type: none"> Extended age range from 2 years to 6 months for the over-the-counter use based on a large safety database (14,291 patients) 	B	Whitehall	7/1/1998	
389.	12/8/1999	Alocril	nedocromil	Allergic Conjunctivitis	<u>Labeling</u>	<ul style="list-style-type: none"> Approved down to 3 years of age 	R	Allergan	NA	
390.	11/8/1999	Omnicef	cefdinir	Bronchitis	<u>Labeling</u>	<ul style="list-style-type: none"> Approved for use in adolescents 	R	Abbott	NA	
391.	10/22/1999	Zantac	ranitidine	Gastroesophageal Reflux	<u>Labeling</u>	<ul style="list-style-type: none"> Small studies in newborns 0 to 1 month receiving ECMO did not demonstrate efficacy but provided information on dose and PK 	B	Glaxo	1/19/1999	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics)	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
392.	9/17/1999	Accolate Tablets	zafirlukast	Prophylaxis and chronic treatment of asthma		<ul style="list-style-type: none"> Approved down to 7 years of age; efficacy extrapolated from demonstrated efficacy in patients 15 years and older 	R	AstraZeneca	NA	
393.	8/24/1999	Cefin Oral Suspension	cefuroxime	Acute bacterial sinusitis		<ul style="list-style-type: none"> Approved down to 3 years of age 	R	Lifecycle Ventures	NA	
394.	8/18/1999	Derma-Smoother/FS Topical Oil	fluocinolone	Atopic dermatitis	<u>Labeling</u>	<ul style="list-style-type: none"> Approved down to 6 years of age; previously approved in adults only 	R	Hill	NA	
395.	7/26/1999	Relenza Rotadisk	zanamivir	Treatment of influenza A and B	<u>Labeling</u>	<ul style="list-style-type: none"> New indication approved down to 12 years of age 	R	GlaxoSmithKline	NA	
396.	7/23/1999	Topamax Tablets	topiramate	Adjunctive treatment of partial onset seizures and generalized tonic clonic seizures	<u>Labeling</u>	<ul style="list-style-type: none"> Approved down to 2 years of age 	R	Ortho-McNeil	NA	
397.	7/14/1999	Omnicef	cefdinir	Otitis media	<u>Labeling</u>	<ul style="list-style-type: none"> Approved 5-day treatment regimen; previously labeled for a 5-10 day treatment regimen 	R	Abbott	NA	
398.	7/9/1999	Tagamet HB 200 Liquid OTC	cimetidine	Heartburn and indigestion	<u>Labeling</u>	<ul style="list-style-type: none"> New indication approved down to 12 years of age; new OTC suspension 	R	GlaxoSmithKline	NA	
399.	7/2/1999	Zaditor Ophthalmic Soln.	ketotifen fumarate	Allergic conjunctivitis	<u>Labeling</u>	<ul style="list-style-type: none"> Approved down to 3 years of age; efficacy extrapolated from adult data 	R	Novartis	NA	
400.	6/17/1999	Cutivate Cream	fluticasone propionate	Treatment of corticosteroid responsive dermatoses	<u>Labeling</u>	<ul style="list-style-type: none"> Extended the age range from 5 years down to 3 months of age 	R	Elan	NA	
401.	4/15/1999	Motrin	ibuprofen	Fever, minor aches & pain, cold symptoms	<u>Labeling</u>	<ul style="list-style-type: none"> Extended age range from 2 years to 6 months for the over-the-counter use based on a large safety database (27,000 patients) 	B	McNeil	7/1/1998	
402.	12/17/1998	Ziagen	abacavir	HIV infection	<u>Labeling</u>	<ul style="list-style-type: none"> Labeling for 3 months - 12 years Information on dose, efficacy, PK 	B	GlaxoSmithKline	12/14/1998	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics●) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
403.	10/15/1998	Versed	midazolam	Sedation/anxiolysis/ amnesia	<u>Labeling</u>	<p>parameters and AE profile</p> <ul style="list-style-type: none"> Specified the effective dose, effective dose range, and time of onset Defined volume of distribution and similarity to adult protein binding and elimination Additional information on AE's and warnings about concomitant medications Identified a subpopulation (children with congenital heart disease and pulmonary hypertension) at higher risk for AE's and the need to start therapy at the lower end of the dosing range 	B	Roche	9/18/1998	
404.	2/10/1998	Amerge	naratriptan	Migraine	<u>Labeling</u>	<ul style="list-style-type: none"> Summary pending 	R	Glaxo Wellcome	NA	

Products in this table fell within the scope of the Pediatric Rule, the Best Pharmaceuticals for Children Act (BPCA), and the Pediatric Research Equity Act (PREA), and contain new pediatric information. The products marked with a (#) are PREA labeling changes that were not based on information from clinical trials in pediatric patients. All other labeling changes are based on information from clinical trials in pediatric patients. This list only serves to highlight key information affecting the pediatric population at the time the particular application was approved resulting from the studies performed for the Pediatric Rule, BPCA and PREA. Biologics have a solid dot (●) by the proper name.

Helpful Links:

Drug and therapeutic biological labeling: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>

Biological labeling and reviews: <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm122938.htm>.

BPCA 2002 Review Summaries: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm161894.htm>

FDAAA Full Reviews: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049872.htm>

Legend:

PK – Pharmacokinetics PD – Pharmacodynamics

Notes:

1. Some products have multiple rows. This is because there is more than one condition covered by the paediatric investigation plan.
2. The data are not to be taken for absolute truth. Study completion dates can change.
3. The data have been extracted from our internal database. Data entry can and does occasionally occur.

Appl. N.	Substances	All studies completion Date	Condition-Indication
EMA-000007-PIP01-07	Ezetimibe	2011/1/31	Treatment of hypercholesterolaemia
EMA-000014-PIP01-07-M04	paliperidone	2012/6/30	Schizoaffective disorder
EMA-000014-PIP01-07-M04	paliperidone	2012/6/30	Schizophrenia
EMA-000015-PIP01-07-M02	Doripenem monohydrate	2012/12/31	Treatment of bacterial infections: complicated intra-abdominal infections
EMA-000015-PIP01-07-M02	Doripenem monohydrate	2012/12/31	Treatment of bacterial infections: complicated urinary tract infections, including complicated and uncomplicated pyelonephritis and cases with concurrent bacteremia
EMA-000015-PIP01-07-M02	Doripenem monohydrate	2012/12/31	Treatment of bacterial infections: nosocomial pneumonia, including ventilator-associated pneumonia
EMA-000018-PIP01-07-M01	Tapentadol hydrochloride	2014/9/30	Acute pain
EMA-000019-PIP02-07-M01	Everolimus	2012/9/30	Angiomyolipoma
EMA-000019-PIP02-07-M01	Everolimus	2012/9/30	Subependymal giant cell astrocytoma
EMA-000020-PIP01-07	maraviroc	2014/12/31	Human immunodeficiency virus infection
EMA-000022-PIP01-07-M04	Rosuvastatin calcium	2014/4/30	Prevention of cardiovascular events
EMA-000022-PIP01-07-M04	Rosuvastatin calcium	2014/4/30	Treatment of homozygous familia hypercholesterolaemia
EMA-000022-PIP01-07-M04	Rosuvastatin calcium	2014/4/30	Treatment of primary combined (mixed) dyslipidaemia
EMA-000022-PIP01-07-M04	Rosuvastatin calcium	2014/4/30	Treatment of primary hypercholesterolaemia (including heterozygous hypercholesterolaemia)
EMA-000025-PIP01-07-M01	Mometasone furoate, Formoterol fumarate	2012/6/30	Persistent asthma
EMA-000027-PIP01-07	Tifacogin	2013/9/30	Septicaemia
EMA-000035-PIP01-07-M02	Tiotropium bromide, used as monohydrate	2012/12/31	Cystic Fibrosis

EMEA-000036-PIP01-07-M04	13 valent pneumococcal polysaccharide conjugate vaccine: - Pneumococcal Polysaccharide Serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F - Diphtheria CRM197 Conjugate	2014/12/31	Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants and children from 6 weeks to 5 years of age.
EMEA-000038-PIP01-07-M03	Darunavir	2011/11/30 2013/5/31 2013/5/31	Darunavir, co-administered with low-dose ritonavir, is indicated in combination with other antiretroviral medicinal products, for the treatment of Human Immunodeficiency Virus (HIV-1) infection in adults and in children and adolescents between 3 and 18 years Treatment of Tourette Syndrome Treatment of restless legs syndrome
EMEA-000041-PIP01-07	Pramipexole dihydrochloride monohydrate		
EMEA-000041-PIP01-07	Pramipexole dihydrochloride monohydrate		
EMEA-000042-PIP01-07-M01	N-Acetyl-L-Cysteine (corresponds to L-Cysteine), L-Alanine, L-Alanyl-L-Glutamine (corresponds to L-Alanine and L-Glutamine), L-Arginine, Glycine, Glycyl-L-Tyrosine (corresponds to Glycine and L-Tyrosine), L-Histidine, L-Isoleucine, L-Leucine, L-Lysine acetate (corresponds to L-Lysine), L-Methionine, L-Phenylalanine, L-Proline, L-Serine, L-Taurine, L-Threonine, L-Tryptophan, L-Valine	2011/12/31	This product is aimed to be used where parenteral nutrition is required.
EMEA-000044-PIP01-07	TGPIPTH1-34 L-Asparaginy-L-glutaminy-L-glutamyl-L-glutaminy-L-valyl-L-seryl-L-prolyl-L-leucyl-L-tyrosyl-L-lysil-L-asparaginy-L-arginyl-L-seryl-L-valyl-L-seryl-L-glutamyl-L-isoleucyl-L-glutaminy-L-leucyl-L-methionyl-L-histidyl-L-asparaginy-L-leucyl-L-glycyl-L-lysyl-L-histidyl-L-leucyl-L-asparaginy-L-seryl-L-methionyl-L-glutamyl-L-arginyl-L-valyl-L-glutamyl-L-tryptophanyl-L-leucyl-L-arginyl-L-lysyl-L-leucyl-L-leucyl-L-aspartyl-L-valyl-L-histidyl-L-asparaginy-L-phenylalanine-, acetate salt	2016/6/30 2014/6/30	Solitary Bone Cyst (ICD 10 CODE M 85.4) Atherothrombotic events
EMEA-000050-PIP01-07-M01	clopidogrel	2014/6/30	Prevention of thrombosis and thromboembolic events in children at risk
EMEA-000050-PIP01-07-M01	clopidogrel	2011/10/31	Medullary thyroid carcinoma
EMEA-000052-PIP01-07	Vandetanib	2012/3/31	Dyslipidaemia in Diabetes Mellitus II (NIDDM)
EMEA-000054-PIP01-07	Pitavastatin calcium	2012/3/31	Familial mixed (combined) hypercholesteraemia
EMEA-000054-PIP01-07	Pitavastatin calcium	2012/3/31	Heterozygous familial hypercholesteraemia
EMEA-000054-PIP01-07	Pitavastatin calcium	2012/3/31	Homozygous familial hypercholesteraemia
EMEA-000055-PIP01-07-M03	Flabeprazole sodium	2014/7/31	Duodenal ulcer

EMA-000055-PIP01-07-M03	Rabeprazole sodium	2014/7/31	Gastric ulcer
EMA-000055-PIP01-07-M03	Rabeprazole sodium	2014/7/31	Gastro-oesophageal reflux disease (GORD)
EMA-000055-PIP01-07-M03	Rabeprazole sodium	2014/7/31	Helicobacter pylori infection in patients with peptic ulcer disease
EMA-000055-PIP01-07-M03	Rabeprazole sodium	2014/7/31	Zollinger-Ellison-Syndrome
EMA-000056-PIP01-07	Bevacizumab	2014/9/30	Non-rhabdomyosarcoma soft tissue sarcoma
EMA-000056-PIP01-07	Bevacizumab	2014/9/30	Rhabdomyosarcoma
EMA-000057-PIP01-07-M02	zoledronic acid	2012/12/31	Osteoporosis
EMA-000057-PIP01-07-M02	zoledronic acid	2012/12/31	Paget's disease of the bone
EMA-000060-PIP01-07-M02	Canakinumab		Cryopyrin Associated Periodic Syndromes (CAPS) including: - Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU), - Muckle-Wells Syndrome (MWS); - Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA). Systemic-onset Juvenile Idiopathic Arthritis
EMA-000060-PIP02-08-M01	Canakinumab	2013/6/30	Children with HBe-Antigen (HBeAg)-negative compensated chronic hepatitis B
EMA-000065-PIP01-07	telbivudine	2017/9/30	Children with HBe-Antigen (HBeAg)-positive compensated chronic hepatitis B
EMA-000065-PIP01-07	telbivudine	2017/9/30	Treatment of chronic hepatitis B in children, adolescents and adult patients with decompensated liver disease.
EMA-000065-PIP01-07	telbivudine	2017/9/30	children with chronic hepatitis B in the immunotolerant phase
EMA-000069-PIP01-07-M01	mepolizumab	2015/6/30	Eosinophilic Esophagitis
EMA-000069-PIP01-07-M01	mepolizumab	2015/6/30	Hyper eosinophilic Syndrome
EMA-000078-PIP01-07-M01	Cinacalcet (as hydrochloride)	2015/2/28	Reduction of hypercalcaemia in patients with parathyroid carcinoma
EMA-000078-PIP01-07-M01	Cinacalcet (as hydrochloride)		Reduction of hypercalcaemia in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated.
EMA-000078-PIP01-07-M01	Cinacalcet (as hydrochloride)	2015/2/28	Treatment of secondary hyperparathyroidism (HPT) in patients with end-stage renal disease (ESRD) on maintenance dialysis therapy
EMA-000080-PIP01-07	Pramipexole dihydrochloride monohydrate	2013/5/31	Treatment of Tourette Syndrome

EMEA-000080-PIP01-07	Pramipexole dihydrochloride monohydrate	2013/5/31	Treatment of restless legs syndrome
EMEA-000081-PIP01-07-M02	dabigatran etexilate given as mesilate	2017/6/30	Prevention of thromboembolic events
EMEA-000081-PIP01-07-M02	dabigatran etexilate given as mesilate	2017/6/30	Treatment of thromboembolic events
EMEA-000084-PIP02-10	Rizatriptan benzoate	2011/6/30	Treatment of migraine
EMEA-000087-PIP01-07	Fingolimod hydrochloride	2015/6/30	Multiple sclerosis
EMEA-000100-PIP01-07-M01	Iron, aqua carbonate hydroxy oxo starch sucrose complex	2014/12/31	Hyperphosphataemia in chronic kidney disease
EMEA-000115-PIP01-07-M01	Ataluren	2013/12/31	Dystrophinopathy
EMEA-000116-PIP01-07-M02	Retigabine	2017/2/28	Epilepsy with partial onset seizures
EMEA-000117-PIP01-07-M02	Retigabine	2017/2/28	Lennox-Gastaut Syndrome
EMEA-000117-PIP01-07	ipilimumab	2014/9/31	Solid malignant tumours
EMEA-000120-PIP01-07-M01	Tigecycline	2012/11/30	Complicated intra-abdominal infections
EMEA-000120-PIP01-07-M01	Tigecycline	2012/11/30	Complicated skin and soft tissue infections
EMEA-000120-PIP01-07-M01	Tigecycline	2012/11/30	Diabetic foot infections
EMEA-000122-PIP01-07-M01	Vicriviroc maleate	2014/12/31	Human Immunodeficiency Virus (HIV-1) Infection
EMEA-000124-PIP01-07-M01	Influenza virus surface antigens (haemagglutinin (HA) and neuraminidase) A/Solomon Islands/3/2006 (H1N1) like strain (A/Solomon Islands/3/2006, IVR-145) A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005, NYMC X161B) B/Malaysia/2506/2004 like strain (B/Malaysia/2506/2004)		
EMEA-000127-PIP01-07	formoterol fumarate, fluticasone propionate	2016/7/31	Influenza
EMEA-000128-PIP01-07-M01	liraglutide	2013/12/31	Asthma
EMEA-000130-PIP01-07	Paracetamol, Eur. Ph.	2013/7/31	Type 2 diabetes mellitus
EMEA-000134-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1)	2011/9/30	Moderate pain and fever
EMEA-000139-PIP01-07	N.meningitidis 287-953 purified antigen, N.meningitidis936-741 purified antigen, N.meningitidis Outer Membrane Vesicles (OMV) from NZ 98/254 strain, N.meningitidis 961c purified antigen	2012/9/30	Influenza infection caused by an influenza strain contained in the vaccine or related to a strain contained in the vaccine
EMEA-000144-PIP01-07	aprepitant	2013/1/31	Meningococcal meningitis
EMEA-000144-PIP01-07	aprepitant	2011/12/31	Nausea and vomiting associated with emetogenic cancer chemotherapy
EMEA-000147-PIP01-07	Dienogest	2011/12/31	Nausea and vomiting associated with postoperative nausea and vomiting
		2013/6/30	Endometriosis

EMA-000149-PIP01-07-M02	Influenza virus surface antigens (haemagglutinin and neuraminidase) of 3 strains recommended annually by WHO for immunization, adjuvanted with MF59C.1.	2016/7/31	Prevention of influenza
EMA-000153-PIP01-07	Dihydroartemisinin, Piperazine phosphate anhydride	2011/6/30	Uncomplicated malaria caused by Plasmodium falciparum
EMA-000154-PIP01-07	Casopitant	2013/5/31	Chemotherapy-induced nausea and vomiting
EMA-000154-PIP01-07	Casopitant	2013/5/31	Post-operative nausea and vomiting
EMA-000156-PIP01-07-M01	Antigen of pre-pandemic strain* A/Vietnam/1203/2004 *propagated in Vero cells (continuous cell line of mammalian origin)	2012/12/31	Influenza infection caused by an influenza strain contained in the vaccine or related to a strain contained in the vaccine
EMA-000160-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1)	2012/9/30	Influenza infection caused by an influenza strain contained in the vaccine or related to a strain contained in the vaccine
EMA-000163-PIP01-07	thrombin alfa	2012/1/31	Haemorrhage complicating a surgical procedure
EMA-000167-PIP01-07	Human normal immunoglobulin	2014/6/30	Idiopathic thrombocytopenic purpura (ITP) as model for immunomodulation
EMA-000167-PIP01-07	Human normal immunoglobulin	2014/6/30	Neonatal haemolytic disease (ABO - Rh-incompatibility)
EMA-000167-PIP01-07	Human normal immunoglobulin	2014/6/30	Primary immunodeficiency (PID) as model for replacement therapy
EMA-000170-PIP01-07-M02	Eltrombopag	2014/12/31	Idiopathic Thrombocytopenia Purpura (ITP)
EMA-000172-PIP01-07	methoxy polyethylene glycol - epoetin beta	2013/6/30	Symptomatic anaemia associated with chronic kidney disease
EMA-000174-PIP01-07-M02	Plerixafor	2017/6/30	Myelosuppression caused by chemotherapy to treat malignant disorders, which requires an autologous haematopoietic stem cell transplant.
EMA-000176-PIP01-07-M02	colistimethate sodium	2011/6/30	Pseudomonas aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis
EMA-000178-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/05 (H5N1)	2012/9/30	Influenza infection caused by an influenza strain contained in the vaccine or related to a strain contained in the vaccine
EMA-000181-PIP01-08	cannabidiol, delta-9-tetrahydrocannabinol	2015/12/31	Intractable spasticity
EMA-000184-PIP01-08	Tobramycin	2012/9/30	Pseudomonas aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis
EMA-000185-PIP01-08-M03	Catridecacog	2011/10/31	Hereditary deficiency of other clotting factors.
EMA-000189-PIP01-08-M01	eptacog alfa pegol (activated)	2016/4/30	Deficiency of factor XIII (fibrin-stabilizing)
EMA-000191-PIP01-08-M01	voriconazole	2012/9/30	Hereditary factor VIII and factor IX deficiency VFEND in combination with ECALTA for the treatment of invasive aspergillosis

EMA-000191-PIP01-08-M01	voriconazole			2012/9/30	VFEND is currently indicated in: Fluconazole-resistant serious invasive Candida infections (Including C. krusei)
EMA-000191-PIP01-08-M01	voriconazole			2012/9/30	VFEND is currently indicated in: Candidaemia in non-neutropenic patients
EMA-000191-PIP01-08-M01	voriconazole			2012/9/30	VFEND is currently indicated in: Invasive aspergillosis
EMA-000191-PIP01-08-M01	voriconazole			2012/9/30	VFend is currently indicated in: Serious fungal infections caused by <i>Scedosporium</i> spp. and <i>Fusarium</i> spp.
EMA-000196-PIP01-08	Telaprevir			2014/6/30	Chronic hepatitis C
EMA-000200-PIP01-08-M01	Saxagliptin			2015/3/31	Type 2 diabetes
EMA-000201-PIP01-08-M01	Skimmed cow's milk powder			2011/5/31	Cow's milk allergy
EMA-000205-PIP01-08	ceftibiprole medocartil sodium			2012/12/31	complicated skin and soft tissue infections
EMA-000207-PIP01-08	Treprostinil			2017/12/31	Other secondary pulmonary hypertension
EMA-000207-PIP01-08	Treprostinil			2017/12/31	Primary pulmonary hypertension
EMA-000221-PIP01-08	Glucose (monohydrate)			2011/12/31	Pain
EMA-000222-PIP01-08-M02	etravirine				Intence is indicated in combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of HIV-1 infection in children 2 months of age and older.
EMA-000265-PIP01-08-M01	golimumab			2014/12/31	Ankylosing Spondylitis
EMA-000265-PIP01-08-M01	golimumab			2013/9/30	Juvenile Idiopathic Arthritis
EMA-000265-PIP01-08-M01	golimumab			2013/9/30	Psoriatic Arthritis
EMA-000265-PIP01-08-M01	golimumab			2013/9/30	Rheumatoid Arthritis
EMA-000266-PIP01-08	Nalfurafine Hydrochloride			2013/12/31	Severe uraemic pruritus
EMA-000274-PIP01-08	telcagepant			2014/12/31	Migraine with or without aura
EMA-000275-PIP01-08	rolofylline			2017/12/31	Heart Failure
EMA-000277-PIP01-08	Hydrocortisone, Calcipotriol Hydrate			2011/3/31	Psoriasis vulgaris
EMA-000279-PIP01-08	raltegravir			2014/12/31	Human immunodeficiency virus (HIV-1) infection
EMA-000281-PIP01-08-M02	huMab IGF-1R - A Recombinant Human Monoclonal Antibody to the Insulin-Like Growth Factor-1 Receptor				Ewing sarcoma family of tumours (including Ewing sarcoma of bone, peripheral primitive neuroectodermal tumour, extraskeletal Ewing sarcoma, and Askin tumour)
EMA-000282-PIP01-08	clevidipine butyrate			2016/12/31	Hypertensive disease
EMA-000284-PIP01-08	Modified Grass Pollen Extract			2012/3/31	Acute atopic conjunctivitis
EMA-000284-PIP01-08-M01	Modified Grass Pollen Extract			2013/12/31	Acute atopic conjunctivitis
EMA-000288-PIP01-08-M02	Moxifloxacin hydrochloride			2014/12/31	Allergic rhinitis due to pollen Acute atopic conjunctivitis
EMA-000288-PIP01-08-M02	Moxifloxacin hydrochloride			2013/4/30	Acute Bacterial Sinusitis
EMA-000288-PIP01-08-M02	Moxifloxacin hydrochloride			2013/4/30	Acute Exacerbation of Chronic Bronchitis

EMA-000288-PIP01-08-M02	Moxifloxacin hydrochloride	2013/4/30	Community Acquired Pneumonia
EMA-000288-PIP01-08-M02	Moxifloxacin hydrochloride	2013/4/30	Complicated Skin and Skin Structure Infections
EMA-000288-PIP01-08-M02	Moxifloxacin hydrochloride	2013/4/30	Pelvic Inflammatory Disease
EMA-000288-PIP01-08-M02	Moxifloxacin hydrochloride	2013/4/30	complicated Intra-Abdominal Infection (cIAI)
EMA-000290-PIP01-08	Nilotinib	2015/9/30	Chronic myelogenous leukemia (CML)
EMA-000290-PIP01-08	Nilotinib	2015/9/30	Gastrointestinal stromal tumors (GIST)
EMA-000292-PIP01-08	alipogene tiparovec	2013/12/31	Hyperchylomicronaemia
EMA-000293-PIP02-10	Pegloticase	2017/6/30	Prevention of Hyperuricaemia
EMA-000293-PIP02-10	Pegloticase	2017/6/30	Treatment of Hyperuricaemia
EMA-000298-PIP01-08	Peginterferon alfa-2a	2014/3/31	Treatment of chronic hepatitis B
EMA-000298-PIP01-08	Peginterferon alfa-2a	2014/3/31	Treatment of chronic hepatitis C
EMA-000299-PIP01-08-M02	Etanercept	2011/6/30	Juvenile idiopathic arthritis
EMA-000299-PIP01-08-M02	Etanercept	2011/6/30	Plaque psoriasis
EMA-000300-PIP01-08	Pitavastatin calcium	2012/3/31	Dyslipidaemia in Diabetes Mellitus II (NIDDM)
EMA-000300-PIP01-08	Pitavastatin calcium	2012/3/31	Familial mixed (combined) hypercholesterolaemia
EMA-000300-PIP01-08	Pitavastatin calcium	2012/3/31	Heterozygous familial hypercholesterolaemia
EMA-000300-PIP01-08	Pitavastatin calcium	2012/3/31	Heterozygous familial hypercholesterolaemia
EMA-000301-PIP01-08	Pitavastatin calcium	2012/3/31	Homozygous familial hypercholesterolaemia
EMA-000301-PIP01-08	Pitavastatin calcium	2012/3/31	Dyslipidaemia in Diabetes Mellitus II (NIDDM)
EMA-000301-PIP01-08	Pitavastatin calcium	2012/3/31	Familial mixed (combined) hypercholesterolaemia
EMA-000301-PIP01-08	Pitavastatin calcium	2012/3/31	Heterozygous familial hypercholesterolaemia
EMA-000302-PIP01-08	Pitavastatin calcium	2012/3/31	Homozygous familial hypercholesterolaemia
EMA-000302-PIP01-08	Pitavastatin calcium	2012/3/31	Dyslipidaemia in Diabetes Mellitus II (NIDDM)
EMA-000302-PIP01-08	Pitavastatin calcium	2012/3/31	Familial mixed (combined) hypercholesterolaemia
EMA-000302-PIP01-08	Pitavastatin calcium	2012/3/31	Heterozygous familial hypercholesterolaemia
EMA-000305-PIP01-08-M01	Ulipristal acetate	2011/6/30	Contraception
EMA-000306-PIP01-08	corifollitropin alfa	2012/12/31	Hypogonadotropic hypogonadism
EMA-000308-PIP01-08	rituximab	2014/10/31	Autoimmune arthritis
EMA-000308-PIP01-08	rituximab	2014/10/31	Diffuse large B-cell lymphoma
EMA-000309-PIP01-08-M02	Tocilizumab	2012/9/30	RoActemra is indicated for the treatment of active systemic juvenile idiopathic arthritis in paediatric patients aged 2 years of age onwards, who have responded inadequately to previous therapy with one or more non steroidal anti-inflammatory drugs or systemic corticosteroids. RoActemra can be given as monotherapy or in combination with methotrexate.

EMA-000309-PIP01-08-M02	Tocilizumab			Treatment of active polyarticular course juvenile idiopathic arthritis (rheumatoid factor positive, rheumatoid factor negative and extended oligoarticular arthritis) in patients aged 2 to < 18 years old with active disease who have had an inadequate response or are intolerant to methotrexate. RoActemra can be given alone or in combination with methotrexate.
EMA-000312-PIP01-08-M01	Human coagulation Factor VIII (plus von Willebrand Factor)	2012/9/30		Hereditary Factor VIII deficiency, Haemophilia A
EMA-000312-PIP01-08-M01	Human coagulation Factor VIII (plus von Willebrand Factor)	2014/12/31		Von Willebrand disease
EMA-000315-PIP01-08	4-[(5R)-6,7-Dihydro-5H-pyrrolo[1,2-c]imidazol-5-yl]-3-fluorobenzonitrile	2017/9/30		Essential Hypertension (I10)
EMA-000317-PIP01-08-M01	Rilpivirine	2016/12/31		Human Immunodeficiency Virus (HIV-1) infection in ARV naive patients
EMA-000319-PIP01-08-M01	Sieved freeze-dried allergen extract of Dermatophagoides farinae, Sieved freeze-dried allergen extract of Dermatophagoides pteronyssinus	2012/1/31		allergic rhinitis due to house mites
EMA-000319-PIP01-08-M01	Sieved freeze-dried allergen extract of Dermatophagoides farinae, Sieved freeze-dried allergen extract of Dermatophagoides pteronyssinus	2012/1/31		asthma due to house mites
EMA-000325-PIP01-08	Tapentadol hydrochloride	2016/10/31		Chronic pain
EMA-000331-PIP01-08-M01	Esomeprazole magnesium trihydrate (oral formulations), Esomeprazole sodium (intravenous formulation)	2014/6/30		Duodenal ulcer
EMA-000331-PIP01-08-M01	Esomeprazole magnesium trihydrate (oral formulations), Esomeprazole sodium (intravenous formulation)	2014/6/30		Gastric ulcer
EMA-000331-PIP01-08-M01	Esomeprazole magnesium trihydrate (oral formulations), Esomeprazole sodium (intravenous formulation)	2014/6/30		Gastro-oesophageal reflux disease
EMA-000331-PIP01-08-M01	Esomeprazole magnesium trihydrate (oral formulations), Esomeprazole sodium (intravenous formulation)	2014/6/30		Peptic ulcer, site unspecified
EMA-000331-PIP01-08-M01	Esomeprazole magnesium trihydrate (oral formulations), Esomeprazole sodium (intravenous formulation)	2014/6/30		Zollinger-Ellison syndrome
EMA-000332-PIP01-08-M02	Brivaracetam	2017/12/31		Epilepsy with partial onset seizures

EMA-000332-PIP01-08-M02	Brivaracetam		2017/12/31	Idiopathic generalised epilepsy with primary generalised tonic clonic seizures
EMA-000332-PIP01-08-M02	Brivaracetam		2017/12/31	Neonatal seizures
EMA-000332-PIP01-08-M02	Brivaracetam		2017/12/31	Paediatric epilepsy syndromes
EMA-000334-PIP01-08	Methoxyflurane		2013/1/31	Acute pain
EMA-000335-PIP01-08-M03	N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide		2015/12/31	Cystic Fibrosis (E84 of ICD10)
EMA-000337-PIP01-08	Grass Pollen Preparation		2013/8/31	Grass pollen induced rhinitis or rhinoconjunctivitis
EMA-000339-PIP02-09-M01	entecavir (monohydrate)		2017/12/31	Treatment of chronic hepatitis B
EMA-000342-PIP01-08	Sunitinib malate		2014/6/30	Gastro-intestinal stromal tumour
EMA-000347-PIP01-08	Bilastine		2012/6/30	Allergic rhinoconjunctivitis
EMA-000347-PIP01-08	Bilastine		2012/6/30	Urticaria
EMA-000353-PIP01-08	Maribavir		2013/12/31	Cytomegaloviral disease
EMA-000362-PIP01-08	Aliskiren		2017/3/31	Heart Failure
EMA-000362-PIP01-08	Aliskiren		2017/3/31	Hypertension
EMA-000365-PIP01-08	Osetamivir phosphate		2011/10/31	Influenza
EMA-000366-PIP01-08-M02	Adalimumab		2013/7/31	Ankylosing Spondylitis
EMA-000366-PIP01-08-M02	Adalimumab		2013/7/31	Crohn's Disease
EMA-000366-PIP01-08-M02	Adalimumab		2013/7/31	Juvenile Idiopathic Arthritis
EMA-000366-PIP01-08-M02	Adalimumab		2013/7/31	Psoriasis
EMA-000366-PIP01-08-M02	Adalimumab		2013/7/31	Psoriatic Arthritis
EMA-000366-PIP01-08-M02	Adalimumab		2013/7/31	Rheumatoid Arthritis
EMA-000366-PIP02-09	Adalimumab			Treatment of moderately to severely active Ulcerative colitis
EMA-000367-PIP01-08	Conestat Alfa		2016/12/31	Hereditary angioedema
EMA-000373-PIP02-09-M01	Ferumoxytol		2013/12/31	Iron Deficiency Anaemia
EMA-000380-PIP04-10	Bio (technico) logical Recombinant human monoclonal antibody to human Interleukin (IL)-17A of the IgG1/kappa class		2015/6/30	
EMA-000387-PIP01-08	insulin glargine		2014/3/31	Treatment of chronic non-infectious uveitis
EMA-000387-PIP01-08	insulin glargine		2011/12/31	Treatment of type 1 diabetes mellitus
EMA-000389-PIP01-08	N-[4-(3-amino-1H-indazol-4-yl)phenyl]-N1-(2-fluoro-5-methylphenyl) urea		2011/12/31	Treatment of type 2 diabetes mellitus
			2017/6/30	Solid malignant tumours

EMA-000394-PIP01-08	Purified Tetanus Toxoid, Purified Filamentous Haemagglutinin (FHA), inactivated Type 2 Poliovirus (MEF-1), Purified Pertactin (PRN), inactivated Type 1 Poliovirus (Mahoney), Purified Diptheria Toxoid, Polyrribosylitol phosphate (PRP) from Haemophilus influenzae type b as PRP-OMPC, Hepatitis B Surface Antigen, recombinant (HBsAg), Purified Fimbriae Types 2 and 3 (FIM), Purified Pertussis Toxoid (PT), inactivated Type 3 Poliovirus (Saukett)	2012/10/31	Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / poliovirus types 1, 2 and 3 / against invasive disease caused by Haemophilus influenzae type b / infection caused by all known subtypes of hepatitis B virus
EMA-000395-PIP01-08	Midazolam (as the Hydrochloride salt)	2011/3/31	Epileptic seizures
EMA-000396-PIP01-08	insulin glargine	2011/12/31	Treatment of type 1 diabetes mellitus
EMA-000396-PIP01-08	insulin glargine	2011/12/31	Treatment of type 2 diabetes mellitus
EMA-000406-PIP01-08	fosaprepitant dimeglumine		Nausea and vomiting associated with emetogenic cancer chemotherapy
EMA-000408-PIP01-08-M02	Icatibant acetate	2012/12/31	Symptomatic treatment of acute attacks of hereditary angioedema associated with C1 esterase inhibitor deficiency
EMA-000409-PIP01-08-M01	Sodium (4R,9aS)-5-Hydroxy-4-methyl-6,10-dioxo-3,4,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid 2,4-difluoro-benzylamide	2012/12/31	Treatment of Human Immunodeficiency Virus (HIV) infection
EMA-000412-PIP01-08	Insulin detemir	2013/7/31	Treatment of type I diabetes mellitus
EMA-000412-PIP01-08	Insulin detemir	2013/7/31	Treatment of type II diabetes mellitus
EMA-000415-PIP01-08	Human immunoglobulin	2014/9/30	Dermatopolymyositis
EMA-000425-PIP02-10	bosentan monohydrate	2013/12/31	Other interstitial pulmonary diseases with fibrosis
EMA-000425-PIP02-10	bosentan monohydrate	2013/12/31	Systemic sclerosis
EMA-000425-PIP02-10	bosentan monohydrate	2013/12/31	Treatment of pulmonary hypertension
EMA-000429-PIP01-08	N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid, N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid, N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid, N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid		
EMA-000430-PIP01-08-M01	rivaroxaban	2013/6/30	Meningococcal infection
EMA-000430-PIP01-08-M01	rivaroxaban	2017/10/31	Prevention of atherothrombotic events in patients with a recent acute coronary syndrome
EMA-000430-PIP01-08-M01	rivaroxaban	2017/10/31	Prevention of stroke and non-central nervous system embolism in subjects with non-valvular atrial fibrillation

EMA-000430-PIP01-08-M01	rivaroxaban		2017/10/31	Prevention of venous thromboembolism in adult patients undergoing elective hip and knee replacement surgery
EMA-000430-PIP01-08-M01	rivaroxaban		2017/10/31	Prevention of venous thromboembolism in hospitalised medically ill patients
EMA-000430-PIP01-08-M01	rivaroxaban		2017/10/31	Treatment and secondary prevention of venous thromboembolism
EMA-000431-PIP01-08-M02	fluticasone furoate, triphenylacetic acid - 4-((1R)-2-[(6-[[2-(2,6-dichlorobenzoyloxy)ethoxy]hexyl)amino]-1-hydroxyethyl]-2-(hydroxymethyl)phenol (1:1)		2017/8/31	Asthma
EMA-000434-PIP01-08	ambrisentan		2016/12/31	Primary and secondary pulmonary hypertension
EMA-000436-PIP01-08	Mannitol		2011/4/30	Cystic fibrosis with pulmonary disease
EMA-000454-PIP01-08-M01	Human normal immunoglobulin		2012/12/31	D80-D89 Certain disorders involving the immune mechanism. Primary Immunodeficiency Syndromes
EMA-000456-PIP01-08	Insulin 454		2013/7/31	Type I diabetes mellitus
EMA-000456-PIP01-08	Insulin 454		2013/7/31	Type II diabetes mellitus
EMA-000459-PIP01-08	Prucalopride succinate		2014/12/31	Symptomatic treatment of functional constipation in children aged from 6 months to 18 years
EMA-000459-PIP01-08	Prucalopride succinate			Symptomatic treatment of opioid induced constipation resulting from chronic opioid use in children aged from 2 to 18 years
EMA-000463-PIP01-08-M01	Imatinib mesilate		2014/12/31	Dermatofibrosarcoma protuberans
EMA-000463-PIP01-08-M01	Imatinib mesilate		2011/6/30	Hyper eosinophilic syndrome and/or chronic eosinophilic leukaemia with FIP1L1-platelet-derived growth factor receptor alpha gene re-arrangement
EMA-000463-PIP01-08-M01	Imatinib mesilate		2011/6/30	Kit (CD 117)-positive gastrointestinal stromal tumours
EMA-000463-PIP01-08-M01	Imatinib mesilate		2011/6/30	Myelodysplastic / myeloproliferative diseases associated with platelet-derived growth factor receptor gene re-arrangements
EMA-000463-PIP01-08-M01	Imatinib mesilate		2011/6/30	Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia
EMA-000463-PIP01-08-M01	Imatinib mesilate		2011/6/30	Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia
EMA-000469-PIP01-08-M01	anidulafungin		2013/10/31	ECALTA in combination with VFEND for the treatment of Invasive Aspergillosis in adults and children from 2 to 18 years
EMA-000469-PIP01-08-M01	anidulafungin		2013/10/31	Treatment of invasive candidiasis in non-neutropenic patients 0 to 18 years
EMA-000470-PIP01-08-M01	sitagliptin phosphate monohydrate		2017/10/31	Treatment of type 2 diabetes mellitus

EMEA-000471-PIP01-08-M01	sitagliptin phosphate monohydrate	2017/10/31	Treatment of type 2 diabetes mellitus
EMEA-000472-PIP01-08-M01	sitagliptin phosphate monohydrate	2017/10/31	Treatment of type 2 diabetes mellitus
EMEA-000477-PIP01-08	4-[(4-fluoro-2-methyl-1H-indol-5-yl)oxy]-6-methoxy-7-[3-(pyrrolidin-1-yl)propoxy]quinazoline maleate, Cediranib	2015/12/31	High-grade glioma
EMEA-000479-PIP01-08	Insulin 454 Insulin aspart	2014/8/31	Type I diabetes mellitus
EMEA-000479-PIP01-08	Insulin 454 Insulin aspart	2014/8/31	Type II diabetes mellitus
EMEA-000482-PIP01-08	Teduglutide (gly2) recombinant human glucagon-like peptide)	2017/2/28	Treatment of short bowel syndrome
EMEA-000485-PIP01-08	Tapentadol hydrochloride	2016/10/31	Chronic pain
EMEA-000486-PIP01-08	Tapentadol hydrochloride	2016/10/31	Chronic Pain
EMEA-000487-PIP01-08	bromocriptine mesilate	2013/1/31	Type 2 diabetes mellitus
EMEA-000492-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Acute Bacterial Sinusitis
EMEA-000492-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Acute Exacerbation of Chronic Bronchitis
EMEA-000492-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Community Acquired Pneumonia
EMEA-000492-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Complicated Skin and Skin Structure Infections
EMEA-000492-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Pelvic Inflammatory Disease
EMEA-000492-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	complicated Intra-Abdominal Infection (cIA)
EMEA-000493-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Acute Bacterial Sinusitis
EMEA-000493-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Acute Exacerbation of Chronic Bronchitis
EMEA-000493-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Community Acquired Pneumonia
EMEA-000493-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Complicated Skin and Skin Structure Infections
EMEA-000493-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	Pelvic Inflammatory Disease
EMEA-000493-PIP01-08	Moxifloxacin hydrochloride	2011/10/31	complicated Intra-Abdominal Infection (cIA)
EMEA-000494-PIP01-08-M01	Tapentadol hydrochloride	2014/9/30	Acute pain
EMEA-000495-PIP01-08-M01	Tapentadol hydrochloride	2014/12/31	Acute pain
EMEA-000496-PIP01-08	Alogliptin benzoate	2014/6/30	Type 2 diabetes mellitus
EMEA-000498-PIP01-08	linagliptin	2016/9/30	Type 2 Diabetes Mellitus
EMEA-000500-PIP01-08-M01	inactivated poliovirus: type 2 (MEF-1 strain), Bordetella pertussis antigen: Pertactin, Inactivated poliovirus: type 3 (Saukett strain), Diphtheria toxoid, Inactivated poliovirus: type 1 (Mahoney strain), Tetanus toxoid, Bordetella pertussis antigen: Pertussis toxoid, Bordetella pertussis antigen: Filamentous Haemagglutinin	2012/12/31	Active immunisation against infectious diseases caused by Corynebacterium diphtheriae / Clostridium tetani / Bordetella pertussis / poliovirus types 1, 2 and 3
EMEA-000509-PIP02-09-M02	Ertoran	2015/11/30	Sepsis
EMEA-000510-PIP02-10	Tazarotene	2016/7/31	Treatment of Lamellar Ichthyosis
EMEA-000511-PIP01-08-M02	propranolol hydrochloride	2011/7/31	Treatment of proliferating infantile hemangiomas requiring systemic therapy
EMEA-000520-PIP01-08	belimumab	2015/12/31	Systemic lupus erythematosus

EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	For the treatment of chronic hepatitis B in paediatric patients from 2 years of age with compensated liver disease
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Hepatitis B infection: Viread is indicated for the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Hepatitis B infection: Viread is indicated for the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis Hepatitis B infection: Viread is indicated for the treatment of chronic hepatitis B in adolescents and children aged over 2 years with compensated liver disease
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Hepatitis B infection: Viread is indicated for the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Hepatitis B infection: Viread is indicated for the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis Hepatitis B infection: Viread is indicated for the treatment of chronic hepatitis B in adolescents aged 12-18 years with compensated liver disease
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	In combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	In combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in antiretroviral treatment-experienced paediatric patients

EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Marketing Authorisation Application for Oral Powder: HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults, adolescents and children aged 2 years and over.
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Marketing Authorisation Application for Viread 40mg/g Oral Powder: HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults and for the treatment of antiretroviral treatment-experienced adolescents and children aged 2 years and over.
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Marketing Authorisation Application for Viread 40mg/g Oral Powder: HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults, adolescents and children aged 2 years and over.
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Type II Variation to Marketing Authorisation for Viread 245 mg Film-Coated Tablets: HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults and adolescents aged 12-18 years.
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Type II Variation to Marketing Authorisation for Viread 245 mg Film-Coated Tablets: HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults and for the treatment of antiretroviral treatment-experienced adolescents aged 12-18 years.
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Type II Variation to Marketing Authorisation for Viread 245 mg Film-Coated Tablets: HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults, and for the treatment of antiretroviral treatment-experienced adolescents aged 12-18 years.

EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Type II Variation to Marketing Authorisation for Viread 40mg/g Oral Powder: HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults, adolescents and children aged 2 years and over.
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	2016/1/31	Type II Variation to Marketing Authorisation for Viread 40mg/g Oral Powder: HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults, and for the treatment of antiretroviral treatment-experienced adolescents and children aged 2 years and over.
EMA-000548-PIP01-09	Beclometasone dipropionate plus formoterol fumarate dihydrate	2014/4/30	Maintenance therapy of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate: - patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta2-agonist or - patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists in adults, as well as in children aged 5 to 11 years and in adolescents aged 12 to 17 years.
EMA-000549-PIP01-09-M01	Infliximab	2011/7/31	Ankylosing spondylitis
EMA-000549-PIP01-09-M01	Infliximab	2011/7/31	Crohn's disease
EMA-000549-PIP01-09-M01	Infliximab	2011/7/31	Juvenile idiopathic arthritis
EMA-000549-PIP01-09-M01	Infliximab	2011/7/31	Psoriasis
EMA-000549-PIP01-09-M01	Infliximab	2011/7/31	Psoriatic arthritis
EMA-000549-PIP01-09-M01	Infliximab	2011/7/31	Rheumatoid arthritis
EMA-000549-PIP01-09-M01	Infliximab	2011/7/31	Ulcerative colitis
EMA-000551-PIP01-09	Givinostat	2014/4/30	Juvenile Idiopathic Arthritis
EMA-000553-PIP01-09-M01	Lisdexamfetamine dimesylate	2014/10/31	Attention Deficit Hyperactivity Disorder (ADHD)
EMA-000556-PIP01-09	velaglucerase alfa	2015/12/31	Gaucher Disease, Type 2
EMA-000556-PIP01-09	velaglucerase alfa	2015/12/31	Gaucher Disease, Types 1 and 3
EMA-000558-PIP01-09	Human normal immunoglobulin	2016/12/31	Idiopathic thrombocytopenic purpura (ITP)
EMA-000558-PIP01-09	Human normal immunoglobulin	2016/12/31	Primary immunodeficiency (PID)
EMA-000559-PIP01-09-M01	Japanese encephalitis virus (strain SA14-14-2 (inactivated))	2014/12/31	active immunization against Japanese encephalitis in children aged 2 months to <18 years
EMA-000567-PIP01-09-M01	Dasatinib	2014/12/31	Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

EMA-000567-PIP01-09-M01	Dasatinib		2014/12/31	Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia
EMA-000568-PIP01-09-M01	C1 inhibitor solifenacin succinate		2012/12/31	C1 inhibitor deficiency.
EMA-000573-PIP01-09	solifenacin succinate		2014/12/31	Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome
EMA-000573-PIP01-09	solifenacin succinate		2014/12/31	Treatment of detrusor overactivity in children with neurogenic bladder dysfunction
EMA-000575-PIP01-09	Ciclosporin		2013/12/31	Keratocconjunctivitis Sicca
EMA-000575-PIP01-09	Ciclosporin		2013/12/31	Vernal Keratoconjunctivitis
EMA-000576-PIP01-09	(3R,4R)-4-methyl-3-(methyl-1H-pyrrolo[2,3-d]pyrimidin-4-ylamino)- β -oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)			
EMA-000576-PIP01-09	(3R,4R)-4-methyl-3-(methyl-1H-pyrrolo[2,3-d]pyrimidin-4-ylamino)- β -oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)		2017/3/31	Ankylosing spondylarthritis
EMA-000576-PIP01-09	(3R,4R)-4-methyl-3-(methyl-1H-pyrrolo[2,3-d]pyrimidin-4-ylamino)- β -oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)		2017/3/31	Juvenile idiopathic arthritis
EMA-000582-PIP01-09	Rupatadine fumarate		2017/3/31	Rheumatoid arthritis
EMA-000582-PIP01-09	Rupatadine fumarate		2012/7/31	Symptomatic treatment of allergic rhinitis in adults and children over 2 years of age
EMA-000583-PIP01-09-M01	boceprevir		2012/7/31	Symptomatic treatment of chronic idiopathic urticaria in adults and children over 2 years of age
EMA-000585-PIP01-09	Titanium dioxide, Bisotrizole		2016/10/31	Chronic viral hepatitis C
EMA-000599-PIP01-09-M01	Influenza virus surface antigens (haemagglutinin and neuraminidase)* of H5N1 strain * propagated in eggs		2011/12/31	Solar Urticaria
EMA-000606-PIP01-09	Levonorgestrel		2014/10/31	Influenza
EMA-000608-PIP01-09	pagibaximab		2013/3/31	Contraception
EMA-000609-PIP01-09	recombinant human glutamic acid decarboxylase (rhGAD65)		2014/1/31	P36: Bacterial sepsis of newborn
EMA-000614-PIP01-09	fampridine		2017/12/31	Treatment of type 1 diabetes mellitus
EMA-000617-PIP01-09	Clopidogrel		2013/12/31	Multiple sclerosis with walking disability
EMA-000617-PIP01-09	Clopidogrel		2014/6/30	Atherothrombotic events
EMA-000618-PIP01-09	Clopidogrel		2014/6/30	Thromboembolic events
EMA-000618-PIP01-09	Clopidogrel		2014/6/30	Atherothrombotic events
EMA-000618-PIP01-09	Clopidogrel		2014/6/30	Thromboembolic events

EMA-000625-PIP01-09	(2R,3aR,10Z,11aS,12aR,14aR,14aR)-N-(cyclopropylsulfonyl)-2-[[2-(4-isopropyl-1,3-thiazol-2-yl)-7-methoxy-8-methyl-4-quinolyl]oxy]-5-methyl-4,14-dioxo-2,3,3a,4,5,6,7,8,9,11a,12,13,14,14a-tetradecahydrocyclopenta[cyclopropa]g[1,6]diazacyclo-tetradecine-12a(1H)-carboxamide (TMC435)	2016/12/31	Chronic viral hepatitis C
EMA-000627-PIP01-09	Ivabradine hydrochloride	2013/9/30	Angina pectoris
EMA-000627-PIP01-09	Ivabradine hydrochloride	2013/9/30	Chronic heart failure
EMA-000627-PIP01-09	Ivabradine hydrochloride	2013/9/30	Coronary artery disease
EMA-000627-PIP01-09	Ivabradine hydrochloride	2013/9/30	Reduction of heart rate during Multislice Computed Tomography Coronary Angiography (MSCT CA)
EMA-000628-PIP01-09	Ivabradine hydrochloride	2013/9/30	Angina pectoris
EMA-000628-PIP01-09	Ivabradine hydrochloride	2013/9/30	Chronic heart failure
EMA-000628-PIP01-09	Ivabradine hydrochloride	2013/9/30	Coronary artery disease
EMA-000628-PIP01-09	Ivabradine hydrochloride	2013/9/30	Reduction of heart rate during Multislice Computed Tomography Coronary Angiography (MSCT CA)
EMA-000632-PIP01-09	Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, trivalent	2014/11/30	Influenza infection
EMA-000636-PIP01-09	fidaxomicin	2014/12/31	Enterocolitis caused by Clostridium difficile
EMA-000637-PIP02-10	Lanthanum carbonate hydrate	2014/12/31	Treatment of hyperphosphataemia
EMA-000639-PIP02-09	Chlorprocaine Hydrochloride	2012/10/31	Intrathecal anaesthesia
EMA-000648-PIP01-09	taliglucerase alfa	2014/6/30	Gaucher Disease (except acute neuronopathic)
EMA-000648-PIP01-09	taliglucerase alfa	2014/6/30	Gaucher Disease, acute neuronopathic
EMA-000649-PIP01-09	Taspoglutide	2017/3/31	Type 2 diabetes mellitus
EMA-000651-PIP01-09-M01	Cholic acid	2012/12/31	Inborn errors of bile acid synthesis
EMA-000653-PIP01-09	Romiplostim	2015/9/30	Treatment of immune thrombocytopenia (idiopathic thrombocytopenic purpura)
EMA-000653-PIP01-09	Romiplostim	2015/9/30	Treatment of thrombocytopenia associated with myelodysplastic syndrome (disease-related or treatment-related)
EMA-000654-PIP01-09	Human Papillomavirus Type 6 L1 protein, Human Papillomavirus Type 11 L1 protein, Human Papillomavirus Type 45 L1 protein, Human Papillomavirus Type 33 L1 protein, Human Papillomavirus Type 16 L1 protein, Human Papillomavirus Type 31 L1 protein, Human Papillomavirus Type 18 L1 protein, Human Papillomavirus Type 58 L1 protein, Human Papillomavirus Type 52 L1 protein	2012/12/31	Infection by Human Papillomavirus
EMA-000661-PIP01-09-M01	Coagulation Factor IX (Recombinant)	2015/6/30	Hereditary Factor IX Deficiency (Haemophilia B)