EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union

13 December 2021
EMA/25556/2021
Scientific Evidence Generation

Register of deadlines to put a medicinal product on the market

In accordance with Article 33 of the REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006

Disclaimer

This Register may not be exhaustive for non-centrally authorised products.

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Cancidas	EMEA-000010-PIP01-07-M01	caspofungin	Treatment of invasive aspergillosis in adult or paediatric patients who are refractory to or intolerant of amphotericin B, lipid formulations of amphotericin B and / or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy. Empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropaenic adult or paediatric patients.	24/10/2001	26/11/2008	26/11/2010	Yes
PegIntron ViraferonPeg	EMEA-000071-PIP01-07	peginterferon alfa-2b	PegIntron/ViraferonPeg is indicated in a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA. When deciding not to defer treatment until adulthood, it is important to consider that the combination therapy induced a growth inhibition. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case by case basis (see section 4.4)."	25/05/2000	11/11/2009	11/11/2011	Yes
Rebetol	EMEA-000070-PIP01-07	ribavirin	Rebetol is indicated, in a combination regimen with peginterferon alfa-2b or interferon alfa-2b, for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA. 3 When deciding to not to defer treatment until adulthood, it is important to consider that the combination therapy induced a growth inhibition. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case by case basis (see section 4.4).	07/05/1999	11/11/2009	11/11/2011	Yes[1]
Orencia	EMEA-000118-PIP01-07-M01	abatacept	Orencia in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor. Orencia can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate.	21/05/2007	20/01/2010	20/01/2012	Yes
Cozaar	EMEA-000008-PIP01-07	losartan potassium	Treatment of essential hypertension in adults and children and adolescents 6-18 years of age.	23/02/2010	23/02/2010	23/02/2012	Yes

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Xalatan	EMEA-000011-PIP01-07-M03	latanoprost	Reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.	29/05/1997	15/10/2010	15/10/2012	Yes
Pediacel	EMEA-000278-PIP01-08-M01	Purified diphtheria toxoid, Purified tetanus toxoid, Five component acellular pertussis [Purified Pertussis Toxoid (PT), Purified Filamentous Haemagglutinin (FHA), Purified Fimbriae Types 2 and 3 (FIM) and Purified Pertactin (PRN)], Inactivated poliomyelitis vaccine (Vero) – Type 1 (Mahoney), Type 2 (MEF-1) and Type 3 (Saukett), Purified polyribosylribitol phosphate capsular polysaccharide of Haemophilus influenzae type b covalently bound to Tetanus protein (PRP-T)	Pediacel is indicated for primary and booster vaccination against diphtheria, tetanus, pertussis, poliomyelitis and invasive Haemophilus influenzae type b disease in infants and children from the age of 6 weeks up to the fourth birthday. Pediacel should be used in accordance with applicable official recommendations.	03/12/2010	03/12/2010	03/12/2012	Yes
Nexium and associated names	EMEA-000331-PIP01-08-M01	esomeprazole sodium / esomeprazole magnesium trihydrate	Children and adolescents with duodenal ulcers caused by H. Pylori infection.	09/12/2000	15/04/2011	15/04/2013	Yes
Sortis and associated names, As well as: Lipitor, Tahor, Xarator, Zarator, Liprimar, Totalip, Torvast, Cardyl	EMEA-000073-PIP01-07	atorvastatin calcium (trihydrate)	Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol, apolipoprotein B, and triglycerides in patients with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin is also indicated to reduce total-C and LDL-C in patients with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.	03/08/2010	05/05/2011	05/05/2013	Yes
Diovan	EMEA-000005-PIP01-07-M01	valsartan	Treatment of hypertension in children and adolescents 6 - 18 years of age.	12/05/2010	11/05/2011	11/05/2013	Yes
Viramune	EMEA-000391-PIP01-08-M01	nevirapine	Tablets and oral suspension Viramune is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1-infected adults, adolescents, and children of any age (see section 4.4). Prolonged-release tablets Viramune is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1-infected adolescents and children three years and above and able to swallow tablets (see section 4.2 and 4.4).	05/02/1998	05/09/2011	05/09/2013	Yes

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Gardasil	EMEA-000375-PIP01-08-M02	human papillomavirus type 6 L1 protein / human papillomavirus type 11 L1 protein / human papillomavirus type 16 L1 protein / human Papillomavirus type 18 L1	Prevention of premalignant genital lesions (cervical, vulvar, vaginal, anal, perineal, perianal, penile), cervical, anal, perineal, and perianal cancer, and external genital warts (condyloma acuminata) causally related to human papillomavirus (HPV) types 6, 11, 16 and 18 in males.	20/09/2006	16/11/2011	16/11/2013	Yes
Remicade	EMEA-000549-PIP01-09-M01	infliximab	Paediatric Crohn's disease Remicade is indicated for treatment of severe, active Crohn's disease, in children and adolescents aged six to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. Remicade has been studied only in combination with conventional immunosuppressive therapy. Paediatric ulcerative colitis Remicade is indicated for treatment of severely active ulcerative colitis, in paediatric patients aged six to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.	13/08/1999	21/02/2012	21/02/2014	Yes
RotaTeq	EMEA-000967-PIP01-10-M01	rotavirus type P1A[8]/rotavirus type G3/rotavirus type G1/rotavirus type G4/rotavirus type G2	RotaTeq is indicated for the active immunisation of infants from the age of six weeks to 32 weeks for prevention of gastroenteritis due to rotavirus infection. RotaTeq is to be used on the basis of official recommendations.	27/06/2006	21/02/2012	21/02/2014	Yes
Enbrel	EMEA-000299-PIP01-08-M03	etanercept	Juvenile idiopathic arthritis Treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy. Enbrel has not been studied in children aged less than 2 years. Paediatric plaque psoriasis Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	03/02/2000	31/07/2012	31/07/2014	Yes
Glivec	EMEA-000463-PIP01-08-M03	imatinib mesilate	Treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ALL) integrated with chemotherapy.	07/11/2001	27/06/2013	27/06/2015	Yes

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Ezetrol, Ezetimibe MSD-SP and associated names, Viemm and associated names, Zient and associated names	EMEA-000007-PIP01-07-M02	ezetimibe	Treatment of primary hypercholesterolaemia Ezetimibe, co-administered with an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia who are not appropriately controlled with a statin alone. Ezetimibe monotherapy is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia in whom a statin is considered inappropriate or is not tolerated. Treatment of homozygous familial hypercholesterolaemia (HoFH) Authorised indications: Ezetimibe, co-administered with a statin, is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis). Treatment of homozygous sitosterolaemia (phytosterolaemia) Authorised indication: Ezetimibe is indicated as adjunctive therapy to diet for use in patients with homozygous familial sitosterolaemia. **Children and adolescents ≥ 10 years** (pubertal status: boys Tanner Stage II and above and girls who are at least one year post-menarche): No dosage adjustment is required (see section 5.2). The clinical experience in paediatric and adolescent patients (aged 10-17 years old) is, however, limited. When Ezetrol is administered with simvastatina statin, the dosage instructions for simvathe statin, in adolescents children should be consulted. **Children >6 and <10 years**: There is limited data on safety and efficacy in this age group. Ezetrol is not recommended for use in children below age 10 due to insufficient data on safety and efficacy (see section s 5.1 and 5.2). **Children <6 years**: There is no available data on use of Ezetrol in this age group.	17/10/2002	30/07/2013	30/07/2015	Yes
Prezista	EMEA-000038-PIP01-07-M03	darunavir (as ethanolate)	Prezista, 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 adult and paediatric patients from the age of 3 years and at least 15 kg body weight (see section 4.2). In deciding to initiate treatment with Prezista co-administered with low dose ritonavir, careful consideration should be given to the treatment history of the individual patient and the patterns of mutations associated with different agents. Genotypic or phenotypic testing (when available) and treatment history should guide the use of Prezista.	12/02/2007	19/09/2013	19/09/2015	Yes
Invega	EMEA-000014-PIP01-07-M06	paliperidone palmitate/paliperidone	Invega is indicated for the treatment of schizophrenia in adults and in adolescents 15 years and older.	25/06/2007	23/05/2014	23/05/2016	Yes
Baraclude	EMEA-000339-PIP02-09-M03	entecavir monohydrate	Baraclude is also indicated for the treatment of chronic HBV infection in nucleoside naive paediatric patients from 2 to < 18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis.	26/06/2006	22/08/2014	22/08/2016	Yes

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Travatan	EMEA-001271-PIP01-12-M01	travoprost	Decrease of elevated intraocular pressure in paediatric patients aged 2 months to < 18 years with ocular hypertension or paediatric glaucoma (see section 5.1).	27/11/2001	19/12/2014	19/12/2016	Yes
Emend	EMEA-000144-PIP01-07-M05	aprepitant	Capsules: Prevention nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults and adolescents from the age of 12. EMEND 125 mg/80 mg is given as part of combination therapy Powder for oral suspension: Prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in children, toddlers and infants from the age of 6 months to less than 12 years. EMEND powder for oral suspension is given as part of combination therapy.	11/11/2003	17/12/2015	17/12/2017	Yes: Capsule,hard. No: Powder for oral suspension.
Revolade	EMEA-000170-PIP01-07-M03	eltrombopag (olamine)	Revolade is indicated for chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients aged 1 year and above who are refractory to other treatments (e.g. corticosteroids, immunoglobulins) (see sections 4.2 and 5.1)	11/03/2010	04/04/2016	04/04/2018	Pending
HyQvia	EMEA-000872-PIP01-10-M03	human normal immunoglobulin	Replacement therapy in adults, children and adolescents (0-18 years) (≥ 18 years) in: • Primary immunodeficiency syndromes with impaired antibody production (see section 4.4). • Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia (CLL), in whom prophylactic antibiotics have failed or are contra-indicated. • Hypogammaglobulinaemia and recurrent bacterial infections in multiple myeloma (MM) patients. • Hypogammaglobulinaemia in patients pre- and post-allogeneic hematopoietic stem cell transplantation (HSCT).	16/05/2013	01/06/2016	01/06/2018	Pending
Ryzodeg	EMEA-000479-PIP01-08-M03	insulin degludec/insulin aspart	Treatment of diabetes mellitus in adults, adolescents and children from the age of 2 years	21/01/2013	22/07/2016	22/07/2018	Yes
Caprelsa	EMEA-000052-PIP01-07-M03	vandetanib	Caprelsa is indicated for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. Caprelsa is indicated in adults, children and adolescents aged 5 years and older. For patients in whom re-arranged-during-transfection(RET) mutation is not known or is negative, a possible lower benefit should be taken into account before individual treatment decision.	17/02/2012	16/12/2016	16/12/2018	Yes
Celsentri	EMEA-000020-PIP01-07-M05	maraviroc	Celsentri, in combination with other antiretroviral medicinal products, is indicated for treatment-experienced adults, adolescents and children of 2 years of age and older and weighing at least 10 kg infected with only CCR5-tropic HIV-1 detectable	18/09/2007	06/07/2017	06/07/2019	Yes: 150 & 300mg film-coated tablets. No: 20mg/mL oral solution; 25mg and 75mg new strengths for film-coated tablets.

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Kaletra	EMEA-001005-PIP01-10-M01	lopinavir/ritonavir	Kaletra is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected adults, adolescents and children from 14 days and older. The choice of Kaletra to treat protease inhibitor experienced HIV-1 infected patients should be based on individual viral resistance testing and treatment history of patients (see sections 4.4 and 5.1).	19/03/2001	26/07/2017	26/07/2019	Pending
Mimpara	EMEA-000078-PIP01-07-M08	cinacalcet (as hydrochloride)	Treatment of secondary hyperparathyroidism (HPT) in children aged 3 years and older with end-stage renal disease (ESRD) on maintenance dialysis therapy in whom secondary HPT is not adequately controlled with standard of care therapy.	22/10/2004	28/08/2017	28/08/2019	Yes: 30mg, 60mg and 90mg film-coated tablets. No: 1mg, 2.5mg and 5mg granules in capsules for opening.
Humira	EMEA-000366-PIP05-12-M02	adalimumab	Juvenile idiopathic arthritis Polyarticular juvenile idiopathic arthritis: Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see section 5.1). Humira has not been studied in patients aged less than 2 years. Enthesitis-related arthritis: Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy (see section 5.1). Paediatric plaque psoriasis Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. Paediatric Crohn's disease Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies. Paediatric Uveitis Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.	08/09/2003	05/09/2017	05/09/2019	Pending
Firazyr	EMEA-000408-PIP01-08-M05	icatibant	Firazyr is indicated for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older, with C1-esterase-inhibitor deficiency.	11/07/2008	19/10/2017	19/10/2019	Pending
Stribild	EMEA-00970-PIP01-10-M01	elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil	Stribild is indicated for the treatment of HIV-1 infection in adolescents aged 12 to < 18 years weighing ≥ 35 kg who are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild and who have experienced toxicities which preclude the use of other regimens that do not contain tenofovir disoproxil.	24/05/2013	19/10/2017	19/10/2019	Yes

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Tasigna	EMEA-000290-PIP01-08-M04	nilotinib	Tasigna is indicated for the treatment of: • adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase, • paediatric patients with chronic phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib.	19/11/2007	15/11/2017	15/11/2019	Pending
Yervoy	EMEA-000117-PIP02-10-M07	ipilimumab	Yervoy as monotherapy is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults, and adolescents 12 years of age and older (see section 4.4).	13/07/2011	18/01/2018	18/01/2020	Yes
Truvada	EMEA-001091-PIP02-15	tenofovir disoproxil fumarate / emtricitabine	Treatment of HIV-1 infection: Truvada is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults (see section 5.1). Truvada is also indicated for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents (see sections 4.2, 4.4 and 5.1). Pre-exposure prophylaxis (PrEP): Truvada is indicated in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents at high risk (see sections 4.2, 4.4 and 5.1).	20/02/2005	05/02/2018	05/02/2020	Pending
Kineret	EMEA-001212-PIP01-11	anakinra	Periodic fever syndromes Kineret is indicated for the treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above: 1. Cryopyrin-Associated Periodic Syndromes (CAPS) Kineret is indicated for the treatment of CAPS, including: • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA) • Muckle-Wells Syndrome (MWS) • Familial Cold Autoinflammatory Syndrome (FCAS) 2. Familial Mediterranean Fever (FMF) Kineret is indicated for the treatment of Familial Mediterranean Fever (FMF). Kineret should be given in combination with colchicine, if appropriate. Still’s Disease Kineret is indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of Still’s disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still’s Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Kineret can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying antirheumatic drugs (DMARDs).	08/03/2002	06/04/2018	06/04/2020	Pending

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Ivemend	EMEA-000406-PIP01-08-M04	fosaprepitant dimeglumine	Prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults and paediatric patients aged 6 months and older.	11/01/2008	30/04/2018	30/04/2020	Yes
Inovelon	EMEA-000709-PIP01-09-M05	rufinamide	Inovelon is indicated as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 1 years of age and older.	16/01/2007	03/08/2018	03/08/2020	Pending
Isentress	EMEA-000279-PIP01-08-M05	raltegravir	Isentress is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection / ISENTRESS 600 mg film-coated tablets is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, and paediatric patients weighing at least 40 kg.	19/12/2007	23/03/2018	23/03/2020	Pending
RoActemra	EMEA-000309-PIP01-08-M07	tocilizumab	RoActemra is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. RoActemra can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX. RoActemra in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoActemra is indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 2 years of age and older.	15/01/2009	12/04/2018	12/04/2020	Pending
Sprycel	EMEA-000567-PIP01-09-M05	dasatinib (as monohydrate)	Sprycel is indicated for the treatment of paediatric patients with: • newly diagnosed Ph+ CML in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib. • newly diagnosed Ph+ ALL in combination with chemotherapy.	20/11/2006	02/07/2018 (CML & powder for oral suspension) 06/02/2019	02/07/2020 (CML & powder for oral suspension) 06/02/2022 (ALL)	Yes: film-coated tablet. No: 10 mg/mL powder for oral suspension.
Coagadex	EMEA-000971-PIP01-10-M03	human coagulation factor X	Coagadex is indicated for the treatment and prophylaxis of bleeding episodes and for perioperative management in patients with hereditary factor X deficiency. Coagadex is indicated in all age groups.	16/03/2016	27/08/2018	27/08/2020	Yes
Nucala	EMEA-000069-PIP02-10-M08	mepolizumab	Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older.	01/12/2015	27/08/2018	27/08/2020	Yes

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Gilenya	EMEA-000087-PIP01-07-M05	fingolimod (hydrochloride)	Gilenya is indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following groups of adult patients and paediatric patients aged 10 years and older: • Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (for exceptions and information about washout periods see sections 4.4 and 5.1). or • Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.	17/03/2011	22/11/2018	22/11/2020	Pending
Ravicti	EMEA-000297-PIP02-12-M02	glycerol phenylbutyrate	Ravicti is indicated for use as adjunctive therapy for chronic management of patients with urea cycle disorders (UCDs) including deficiencies of carbamoyl phosphate synthetase I (CPS), ornithine carbamoyltransferase (OTC), argininosuccinate synthetase (ASS), argininosuccinate lyase (ASL), arginase I (ARG) and ornithine translocase deficiency hyperornithinaemia-hyperammonaemia homocitrullinuria syndrome (HHH) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).	26/11/2015	18/12/2018	18/12/2020	Pending
Simponi	EMEA-000265-PIP01-08-M04	golimumab	Simponi in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children 2 years of age, who have responded inadequately to previous therapy with MTX.	01/10/2009	18/02/2019	18/02/2021	Yes: 50mg solution for injection in pre-filled pen and in pre-filled syringe. No: 45 mg/0.45 mL solution for injection in pre-filled pen.
Orencia	EMEA-000118-PIP02-10-M03	abatacept	Orencia in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) in paediatric patients 2 years of age and older who have had an inadequate response to previous DMARD therapy. Orencia can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate.	21/05/2007	08/04/2019	08/04/2021	Yes: 125mg solution for injection pre-filled syringe and pen. No: 50 and 87.5 mg solution for injection in pre-

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Mozobil	EMEA-000174-PIP01-07-M03	plerixafor	Mozobil is indicated in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children with lymphoma or solid malignant tumours, either: • pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield, or • who previously failed to collect sufficient haematopoietic stem cells (see section 4.2).	30/07/2009	13/05/2019	13/05/2021	Pending
Zinforo	EMEA-C-000769-PIP01-09-M08	ceftaroline fosamil	Zinforo is indicated for the treatment of the following infections in neonates, infants, children, adolescents and adults(see sections 4.4 and 5.1): • Complicated skin and soft tissue infections (cSSTI) • Community-acquired pneumonia (CAP) Consideration should be given to official guidance on the appropriate use of antibacterial agents.	22/08/2012	25/07/2019	25/07/2021	Yes
Victoza	EMEA-000128-PIP01-07-M08	liraglutide	Victoza is indicated for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications • in addition to other medicinal products for the treatment of diabetes. For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1.	30/06/2009	09/08/2019	09/08/2021	Pending
Lucentis	EMEA-000527-PIP04-13-M01	ranibizumab	Lucentis is indicated in preterm infants for the treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease.	22/01/2007	03/09/2019	03/09/2021	Pending
Benlysta	EMEA-000520-PIP01-08	belimumab	Benlysta is indicated as add-on therapy in patients aged 5 years and older with active, autoantibody positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti dsDNA and low complement) despite standard therapy.	13/07/2011	21/10/2019	21/10/2021	Yes
Stelara	EMEA-000311-PIP01-08-M04	ustekinumab	Stelara is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	15/01/2009	20/01/2020	20/01/2022	Pending

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Dificlir	EMEA-000636-PIP01-09-M07	fidaxomicin	Dificlir film-coated tablets is indicated for the treatment of Clostridioides difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD) in adult and paediatric patients with a body weight of at least 12.5 kg (see section 4.2 and 5.1).	05/12/2011	13/02/2020	13/02/2022	Pending[2]
MabThera	EMEA-000308-PIP01-08-M04	rituximab	MabThera in combination with chemotherapy is indicated for the treatment of paediatric patients (aged ≥ 6 months to < 18 years old) with previously untreated advanced stage CD20 positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL)/Burkitt leukaemia (mature B-cell acute leukaemia) (BAL) or Burkitt-like lymphoma (BLL). MabThera, in combination with glucocorticoids, is indicated for the induction of remission in paediatric patients (aged ≥2 to <18 years old) with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA).	02/06/1998 21/03/2014 (new formulation)	03/03/2020	03/03/2022	Pending
MabThera	EMEA-000308-PIP02-11-M01	rituximab	MabThera in combination with chemotherapy is indicated for the treatment of paediatric patients (aged ≥ 6 months to < 18 years old) with previously untreated advanced stage CD20 positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL)/Burkitt leukaemia (mature B-cell acute leukaemia) (BAL) or Burkitt-like lymphoma (BLL). MabThera, in combination with glucocorticoids, is indicated for the induction of remission in paediatric patients (aged ≥2 to <18 years old) with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis	02/06/1998 21/03/2014 (new formulation)	03/03/2020	03/03/2022	Pending
Intelence	EMEA-000222-PIP01-08-M09	etravirine	Intelence, in combination with a boosted protease inhibitor and other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients and in antiretroviral treatment-experienced paediatric patients from 2 years of age (see sections 4.4, 4.5 and 5.1).	28/08/2008	28/04/2020	28/04/2022	Pending
Ruconest	EMEA-000367-PIP01-08-M08	conestat alfa	Ruconest is indicated for treatment of acute angioedema attacks in adults, adolescents, and children (aged 2 years and above) with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.	28/10/2010	28/04/2020	28/04/2022	Pending
Ecalta	EMEA-000469-PIP01-08-M07	anidulafungin	Treatment of invasive candidiasis in adults and paediatric patients aged 1 month to < 18 years.	20/09/2007	03/06/2020	03/06/2022	Yes
Cablivi	EMEA-001157-PIP01-11-M02	caplacizumab	Cablivi is indicated for the treatment of adults and adolescents of 12 years of age and older weighing at least 40 kg experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.	30/08/2018	09/06/2020	09/06/2022	Pending
Sovaldi	EMEA-001276-PIP01-12-M02	sofosbuvir	Sovaldi is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults and paediatric patients aged 3 years and above (see sections 4.2, 4.4 and 5.1). For hepatitis C virus (HCV) genotype specific activity, see sections 4.4 and 5.1.	16/01/2014	25/06/2020	25/06/2022	Pending

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Harvoni	EMEA-001411-PIP01-12-M04	sofosbuvir / ledipasvir	Harvoni is indicated for the treatment of chronic hepatitis C (CHC) in adult and paediatric patients aged 3 years and above (see sections 4.2, 4.4 and 5.1). For hepatitis C virus (HCV) genotype-specific activity see sections 4.4 and 5.1.	17/11/2014	03/07/2020	03/07/2022	Pending
Latuda	EMEA-001230-PIP01-11-M05	lurasidone hydrochloride	Latuda is indicated for the treatment of schizophrenia in adults and adolescent aged 13 years and over.	21/03/2014	25/08/2020	25/08/2022	Pending
Velphoro	EMEA-001061-PIP01-10-M03	sucroferric oxyhydroxide	Velphoro is indicated for the control of serum phosphorus levels in paediatric patients 2 years of age and older with CKD stages 4-5 (defined by a glomerular filtration rate <30 mL/min/1.73 m²) or with CKD on dialysis.	26/08/2014	16/11/2020	16/11/2022	Pending[2]
Humira	EMEA-000366-PIP02-09-M06	adalimumab	Juvenile idiopathic arthritis • Polyarticular juvenile idiopathic arthritis: Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see section 5.1). Humira has not been studied in patients aged less than 2 years. • Enthesitis-related arthritis: Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy (see section 5.1). Paediatric plaque psoriasis: Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. Paediatric Crohn's disease: Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies. Paediatric Uveitis: Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. Paediatric ulcerative colitis: Humira is indicated for the treatment of moderately to severely active ulcerative colitis in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.	08/09/2003	20/11/2020	20/11/2022	Pending

Product invented name	Paediatric procedure number	Active substance(s)	Authorised paediatric indication(s)	Initial Marketing Authorisation date	Variation date for paediatric indication	Deadline to place product on the market	Product with paediatric indication placed on the marked*
Pradaxa	EMEA-000081-PIP01-07-M11	dabigatran etexilate mesilate	Treatment of VTE and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age. For age appropriate dose forms, see section 4.2.	17/03/2008	11/01/2021	11/01/2023	Pending
Xarelto	EMEA-000430-PIP01-08-M11	rivaroxaban	Xarelto, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.	30/09/2008	21/01/2021	21/01/2023	Pending[2]
Spherox[3]	EMEA-001264-PIP01-12-M02	spheroids of human autologous matrix-associated chondrocytes	Repair of symptomatic articular cartilage defects of the femoral condyle and the patella of the knee (International Cartilage Regeneration & Joint Preservation Society [ICRS] grade III or IV) with defect sizes up to 10 cm^2 in adults and adolescents with closed epiphyseal growth plate in the affected joint.	10/07/2017	28/06/2021	28/06/2023	Pending
Deltyba	EMEA-001113-PIP01-10-M06	delamanid	Deltyba is indicated for use as part of an appropriate combination regimen for pulmonary multidrug resistant tuberculosis (MDR-TB) in adults, adolescents, children and infants with a body weight of at least 10 kg when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.	27/04/2014	16/09/2021	16/09/2023	Pending[2]
Vosevi	EMEA-001822-PIP01-15-M01	sofosbuvir / voxilaprevir / velpatasvir	Vosevi is indicated for the treatment of chronic hepatitis C virus (HCV) infection in patients aged 12 years and older and weighing at least 30 kg.	26/07/2017	16/09/2021	16/09/2023	Pending[2]

**: As declared by Marketing Authorisation Holders; the product needs to be on the market in all Member States where the adult product was already commercialised and within the deadline as per Article 33 of the Paediatric Regulation (No 1906/2006).*

[1] : Notification for withdrawal from the market received on 24/03/2021.

[2] : New formulation (or strength) expected.

[3] : Name change due to Marketing Authorisation; former name: (co.don) chondrosphere