Periodic Report on drugs approved for children under the EU Centralised Procedure

(period: January 2024 – December 2024)

Index

1. Abstract

This is the periodic report prepared by the TEDDY Network on paediatric medicines registered in Europe under the EMA Centralised Procedure from October 1995 to December 2024.[i]

2. Introduction

In the pharmaceutical field the main goal is to guarantee that efficacious, high quality and safe medicines are available to European citizens, regardless of income or social status. The appropriate use of medicines depends on the widespread dissemination of relevant information to all key stakeholders (regulatory agencies, medical doctors, pharmacists, patient associations, industries, etc).

For many years, a lack of information on drugs continued to affect the paediatric population. It is well known that approved medicines are often administered to children without proper information on dosage, potential toxicity, or clinical evidence that supporting their safety and efficacy at recommended doses.

The issue of paediatric medicines has been considered by the European Institutions since 1997. Over the years, various initiatives have been developed to address these challenges, culminating in the European Paediatric Regulation [1], which came into force in January 2007. The Regulation is currently under review by the European Commission.

TEDDY collects and stores in its database (EPMD - European Paediatric Medicines Database) information on paediatric medicines registered in Europe under the EMA Centralised Procedure since October 1995. Reports are released regularly; three publications are available [2,3,4].

The aim of this report is to present the status of paediatric medicines licensed by EMA, offering insight into authorisations and variations up to 2024 (paragraph 5).

3. Methodology

3.1. Data collection and storing

The EMA public website (section "What's new") serves as the primary source of information. For each newly approved medicine, including new Marketing Authorisations (MAs) and variations listed on the EMA website, the European Public Assessment Reports (EPARs) for human medicines are analysed. Information derived by EPARs is collected, standardised and stored in TEDDY European Paediatric Medicines Database (EPMD). Data collection and validation are carried out by two researchers, and any discrepancies are resolved with the assistance of a supervisor.

3.2. Collected data

EPMD includes an extensive amount of information on each medicinal product approved by EMA including:

- Year of approval
- Active substance
- Tradename
- Anatomical Therapeutic Chemical (ATC) code - first-level
- Indication and Paediatric Indication

- Ages for which the drug is intended
- Orphan Drug status

3.3. Data Analysis

General descriptive statistics are conducted annually, providing details on: a) year of MA, b) age of population for which the drug is approved, c) ATC code, and d) orphan status. In addition, the database allows to perform further analyses upon specific request.

4. Results

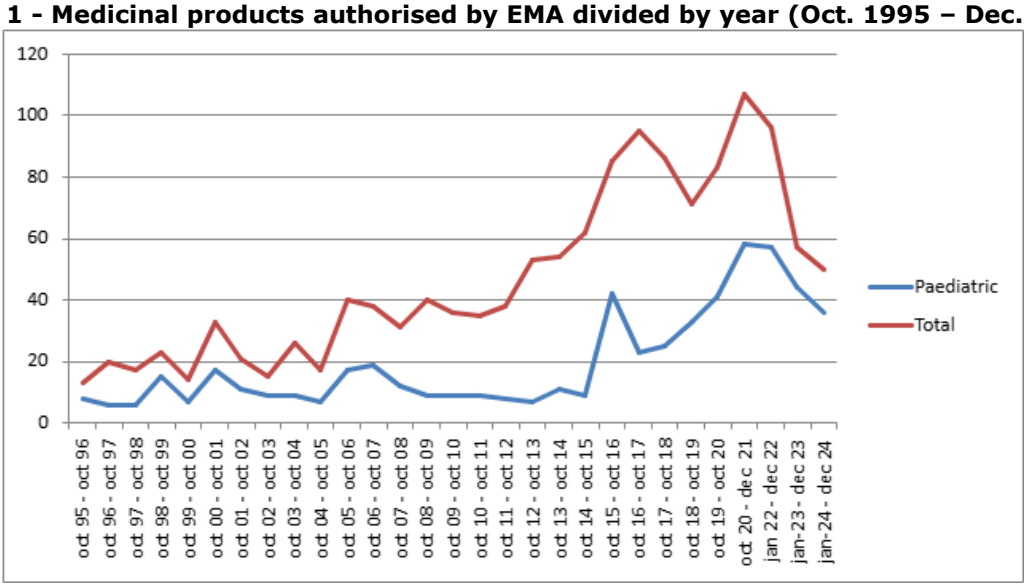
4.1. Number and percentage of paediatric medicines

From the establishment of the EMA institution until December 2024, 1092 active substances (ASs) have been approved under the Centralised Procedure (corresponding to a total of 1761 Medicinal Products): 438 of them were paediatric (40%) out of a total of 722 paediatric Medicinal Products.[1]

Additionally, 22 active substances have been exclusively authorized for the pediatric population.

Figure 1 illustrates the number of paediatric medicines compared to the total number of medicines approved by EMA under the centralised procedure over the years, including new MAs and variations. Despite the increase observed in 2007, the number of paediatric medicines remained low until2015. However, a constant rise has been noted since 2015, with the gap between adult and paediatric approvals appearing significantly reduced in 2022–2024.

Figure 1 - Medicinal products authorised by EMA divided by year (Oct. 1995 – Dec. 2024)

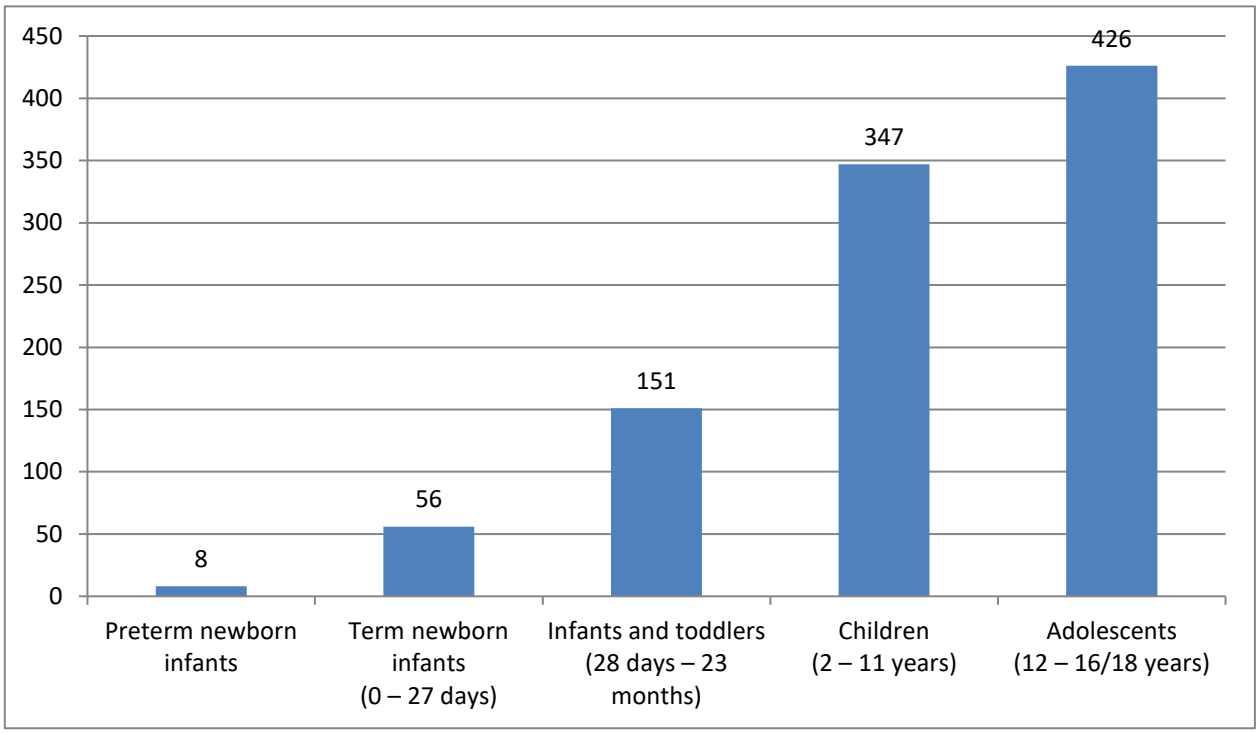


[1] In the first ten years period covered by this report (1995-2005), medicines that included in their documentation (Summary of Product Characteristics – SPC/PL) a paediatric dosages information, but not a paediatric indication, were also considered as paediatric.

4.2. Distribution of paediatric medicines by age

Figure 2 illustrates the distribution of paediatric medicines approved for different age groups. As expected, the data shows that the availability of medicines is lower for neonates and younger children but gradually increases with age, reaching its peak in adolescents.

Figure 2 – Paediatric Medicines: age distribution



4.3. Distribution of paediatric medicines by ATC

Authorised paediatric medicines spans across 14 ATC first-level categories, with significant variation in their distribution among therapeutic areas. The highest proportion is observed in B-ATC "Blood and blood forming organs" (58%), followed by J-ATC "anti-infectives for systemic use" (56%) and A-ATC "Alimentary tract and metabolism" (54%). Contrarily, the lowest proportions are found in L-ATC "Antineoplastic and immunomodulating agents" and M-ATC "Musculo-skeletal system" (both 27%) and G-ATC "Genito-urinary system and sex hormones" (20%). Table 1 provides additional details.

Table 1: EMA Paediatric Medicines by ATC code	**Paediatric/Total**	
	N	**%**
A -Alimentary tract and metabolism	66/121	54
B - Blood and blood forming organs	45/78	58
C - Cardiovascular system	16/56	28
D - Dermatologicals	9/18	50

Table 1: EMA Paediatric Medicines by ATC code	Paediatric/Total	
	N	%
G - Genito-urinary system and sex hormones	7/35	20
H - Systemic hormonal preparations, excluding sex hormones and insulins	10/22	45
J - Anti-infectives for systemic use	112/200	56
L - Antineoplastic and immunomodulating agents	80/294	27
M - Musculo-skeletal system	8/29	27
N - Nervous system	28/87	32
P - Antiparasitic products, insecticides and repellents	2/2	100
R - Respiratory system	16/39	41
S - Sensory organs	10/30	33
V - Various	19/59	32
Not assigned yet	10/22	45
TOTAL	***438/1092***	***40%***

4.4. Distribution of paediatric medicines by orphan status

Regarding orphan drugs, as of December 2024, a total of 142 orphan medicines have been authorised under the OD Regulation by the EMA. Among them, 69 are paediatric medicines. Thus, comparing the proportion of paediatric medicines between orphan and non-orphan drug groups reveals a notable difference, with paediatric medicines representing 48% of orphan drugs, compared to 40% in the non-orphan category.

Table 2 – Paediatric orphan drugs and ATC distribution

ATC	Orphan medicinal products authorised	Paediatric orphan drugs authorised	Percentage
A -Alimentary tract and metabolism	22	19	86
B - Blood and blood forming organs	13	9	69
C - Cardiovascular system	4	0	-
D - Dermatologicals	2	1	50
G- Genito-urinary system and sex hormones	0	0	-
H - Systemic hormonal preparations, excluding sex hormones and insulins	5	4	80
J - Anti-infectives for systemic use	7	3	43
L - Antineoplastic and immunomodulating agents	50	9	18
M - Musculo-skeletal system	4	3	75
N - Nervous system	13	8	61
P -Antiparasitic products, insecticides and repellents	1	1	100
R - Respiratory system	2	2	100

ATC	Orphan medicinal products authorised	Paediatric orphan drugs authorised	Percentage
S - Sensory organs	5	4	80
V -Various	3	1	33
Not assigned yet	11	9	81
TOTAL	**142**	**69**	***48%***

5. New paediatric drug from January 2024 to December 2024

Active substance	ATC code	Paediatric indication	Orphan	Paediatric Age	Variations	PIP
Vamorolone	H02AB18	**AGAMREE** is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients aged 4 years and older.	YES	> 4 years		YES
Alirocumab	C10AX14	Primary hypercholesterolaemia and mixed dyslipidaemia **Praluent** is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and in paediatric patients 8 years of age and older with heterozygous familial hypercholesterolaemia (HeFH) as an adjunct to diet: - in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or, - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.	NO	> 8 years	12/10/23 (15/11/23): Extension of indication to include treatment of paediatric patients 8 years of age and older with heterozygous familial hypercholesterolemia (HeFH) as an adjunct to diet, alone or in combination with other LDL-C lowering therapies.	NO
proteolytic enzymes enriched in bromelain	D03BA03	**NexoBrid** is indicated in all age groups for removal of eschar in patients with deep partial- and fullthickness thermal burns.	NO	All ages	09/11/23 (14/12/23): Extension of current indication for removal of eschar in adults with deep partial- and full-thickness thermal burns to the paediatric population for NexoBrid	YES
Trametinib dimethyl sulfoxide	L01EE01	Low-grade glioma **Spexotras** in combination with dabrafenib is indicated for the treatment of paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. High-grade glioma **Spexotras** in combination with dabrafenib is indicated for the treatment of paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment.	YES	> 1 year		YES
patiromer	V03AE09	**Veltassa** is indicated for the treatment of hyperkalaemia in adults and adolescents aged 12 to 17 years.	NO	> 12 years	09/11/23 (05/01/24): extension the indication to include treatment of population from 12 to 17 years old for Veltassa	YES
empagliflozin	A10BK03	Type 2 diabetes mellitus **Jardiance** is indicated in adults and children aged 10 years and above for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise-as monotherapy	NO	> 10 years	09/11/23 (07/12/23): Extension of indication for JARDIANCE to include treatment of children aged 10	YES

Active substance	ATC code	Paediatric indication	Orphan	Paediatric Age	Variations	PIP
		when metformin is considered inappropriate due to intolerance-in addition toother medicinal products for the treatment of diabetes For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied.			years and above with type 2 diabetes	
Ustekinumab *(Biosimilar)*	L04AC05	Paediatric plaque psoriasis: **Uzpruvo** 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.	NO	> 6 years		NO
Gadopiclenol	V08CA12	This medicinal product is for diagnostic use only. **Elucirem** is indicated in adults and children aged 2 years and older for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and visualization of pathologies with disruption of the blood-brain-barrier (BBB) and/or abnormal vascularity of: - the brain, spine, and associated tissues of the central nervous system (CNS); - the liver, kidney, pancreas, breast, lung, prostate, and musculoskeletal system. It should be used only when diagnostic information is essential and not available with unenhanced MRI.	NO	> 2 years		YES
Gadopiclenol	V08CA12	This medicinal product is for diagnostic use only. **Vueway** is indicated in adults and children aged 2 years and older for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and visualization of pathologies with disruption of the blood-brain-barrier (BBB) and/or abnormal vascularity of: - the brain, spine, and associated tissues of the central nervous system (CNS); - the liver, kidney, pancreas, breast, lung, prostate, and musculoskeletal system. It should be used only when diagnostic information is essential and not available with unenhanced MRI.	NO	> 2 years		YES
latanoprost	S01EE01	**Catiolanze** is indicated for the reduction of elevated IOP in children from 4 years of age and adolescents with elevated IOP and paediatric glaucoma.	NO	> 4 years		NO
Crovalimab	L04AE05	**Velsipity** is indicated for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.	NO	> 16 years		YES
Exagamglogene autotemcel	B06AX05	β-thalassemia: **Casgevy** is indicated for the treatment of transfusion-dependent β-thalassemia (TDT) in patients 12 years of age and older for whom haematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen (HLA)-matched related HSC donor is not available. Sickle cell disease: **Casgevy** is indicated for the treatment of severe sickle cell disease (SCD) in patients 12 years of age and older with recurrent vaso-occlusive crises (VOCs) for whom haematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen (HLA)-matched related HSC donor is not available.	YES	> 12 years		YES
Omaveloxolone	Not yet assigned	**Skyclarys** is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.	YES	> 16 years		YES
Bezlotoxumab	J06BB21	**ZINPLAVA** is indicated for the prevention of recurrence of Clostridioides difficile infection (CDI)	NO	> 1 year	14/12/23 (26/01/24): Extension of indication to include treatment of the	YES

Active substance	ATC code	Paediatric indication	Orphan	Paediatric Age	Variations	PIP
		in adult and paediatric patients 1 year of age and older at high risk for recurrence of CDI			paediatric population (1 to 18 years of age) for ZINPLAVA	
human fibrinogen human thrombin	B02BC	Supportive treatment in patients where standard surgical techniques are insufficient: - for improvement of haemostasis. - as suture support: in vascular surgery. **VeraSeal** is indicated in all age groups.	NO	all ages	14/12/23 (25/01/24): Extension of indication to include treatment of children for VeraSeal	YES
Ibuprofen *(Generic)*	C01EB16	Treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants less than 34 weeks of gestational age.	NO	Preterm infants		NO
pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	J07AL02	Active immunisation for the prevention of invasive disease, pneumonia, and acute otitis media caused by Streptococcus pneumoniae in infants, children, and adolescents from 6 weeks to less than 18 years of age. Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals18years of age and older. **Prevenar20** should be used in accordance with official recommendations.	NO	> 6 weeks to 18 years	25/01/24 (11/03/24): Extension of indication to include infants, children and adolescents from 6 weeks to less than 18 years of age for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae	YES
Dabigatran etexilate mesylate *(Generic)*	B01AE07	Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery. Treatment of VTE and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age.	NO	all ages		NO
abrocitinib	D11AH08	**Cibinqo** is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.	NO	> 12 years	22/02/24 (21/03/24): Extension of indication to include treatment of adolescents 12 to < 18 years of age with moderate to severe atopic dermatitis for CIBINQO	YES
Pegzilarginase	A16AB24	**Loargys** is indicated for the treatment of arginase 1 deficiency (ARG1-D), also known as hyperargininemia, in adults, adolescents and children aged 2 years and older.	YES	> 2 years		YES
influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	J07BB02	**Celldemic** is indicated for active immunisation against H5N1 subtype of Influenza A virus in adults and infants from 6 months of age and above.	NO	> 6 months		YES
influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	J07BB02	**Incellipan** is indicated for active immunisation against influenza in an officially declared pandemic. Incellipan should be used in accordance with official recommendations.	NO	> 6 months		YES
Omalizumab *(Biosimilar)*	R03DX05	Allergic asthma **Omlyclo** is indicated in adults, adolescents and children (6 to < 12 years of age). **Omlyclo** treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma. Adults and adolescents (12 years of age and older) **Omlyclo** is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and who have reduced lung function (FEV1 < 80 %) as well as frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily highdose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Children (6 to < 12 years of age) **Omlyclo** is indicated as add-on therapy to improve asthma	NO	> 6 years		NO

Active substance	ATC code	Paediatric indication	Orphan	Paediatric Age	Variations	PIP
		control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.				
Denosumab *(Biosimilar)*	M05BX04	**Wyost:** Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.	NO	> 12 years		NO
Dopamine hydrochloride	C01CA04	**Neoatricon**. Treatment of hypotension in haemodynamically unstable neonates, infants and children < 18 years.	NO	0-18 years		YES
influenza vaccine (live attenuated, nasal)	J07BB03	Prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age. The use of **Fluenz** should be based on official recommendations.	NO	> 24 months to 18 years		YES
dantrolene sodium, hemiheptahydrate	M03CA01	In combination with adequate support measures, **Agilus** is indicated for the treatment of malignant hyperthermia in adults and children of all ages.	NO	all ages		NO
tocilizumab	L04AC07	**Tofidence** 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. Tofidence can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX. **Tofidence** 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. **Tofidence** can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.	NO	> 2 years		NO
dimethyl fumarate *(Generic)*	L04AX07	**Dimethyl fumarate Neuraxpharm** is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).	NO	>13 years		NO
dimethyl fumarate *(Generic)*	L04AX07	**Dimethyl fumarate Accord** is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).	NO	>13 years		NO
dimethyl fumarate *(Generic)*	L04AX07	**Dimethyl fumarate Mylan** is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).	NO	>13 years		NO
Efanesoctocog alfa	B02BD02	Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). **ALTUVOCT** can be used for all age groups.	YES	All ages		YES
efavirenz emtricitabine tenofovir disoproxil succinate *(Generic)*	J05AR06	Treatment of HIV-1 infection **Emtricitabine/Tenofovir disoproxil Krka** is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults. **Emtricitabine/Tenofovir disoproxil Krka** is also indicated for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents. Pre-exposure prophylaxis (PrEP) **Emtricitabine/Tenofovir disoproxil Krka** is indicated in combination with safer sex practices for preexposure prophylaxis to reduce the risk of	NO	> 12 years		NO

Active substance	ATC code	Paediatric indication	Orphan	Paediatric Age	Variations	PIP
		sexually acquired HIV-1 infection in adults and adolescents at high risk.				
Ustekinumab *(Biosimilar)*	L04AC05	Paediatric plaque psoriasis **Pyzchiva** 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.	NO	> 6 years		NO
Dasatinib *(Generic)*	L01EA02	**Dasatinib Accord Healthcare** 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.	NO	> 1 year		NO
apadamtase alfa cinaxadamtase alfa	B01AD13	**ADZYNMA** is an enzyme replacement therapy (ERT) indicated for the treatment of ADAMTS13 deficiency in children and adult patients with congenital thrombotic thrombocytopenic purpura (cTTP). **ADZYNMA** can be used for all age groups.	YES	all ages		YES
Apixaban	B01AF02	**Eliquis**: Paediatric population Treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age.	NO	> 28 days	30/05/24 (26/07/24): Extension of indication to include the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age for Eliquis (all strengths)	YES
Ustekinumab *(Biosimilar)*	L04AC05	Paediatric plaque psoriasis **WEZENLA** 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.	NO	> 6 years		NO
dasiglucagon	H04AA02	**Zegalogue** is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 6 years and over with diabetes mellitus.	NO	> 6 years		YES
Crovalimab	L04AJ07	**Piasky** as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age or older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria (PNH): • In patients with haemolysis with clinical symptom(s) indicative of high disease activity. • In patients who are clinically stable after having been treated with a complement component 5 (C5) inhibitor for at least the past 6 months.	NO	> 12 years		YES
mirabegron	G04BD12	Neurogenic detrusor overactivity in the paediatric population **Betmiga** prolonged-release tablets are indicated for treatment of neurogenic detrusor overactivity (NDO) in paediatric patients aged 3 to less than 18 years.	NO	> 3 years	27/06/24 (22/08/24): Extension application to introduce a new pharmaceutical form associated with new strength (8 mg/ml prolonged-release granules for oral suspension), grouped with a type II variation (C.I.6.a) to include treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 to less than 18 years.	YES
epinephrine	C01CA24	**EURneffy** is indicated in the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced	NO	Children weight > 30 kg		YES

Active substance	ATC code	Paediatric indication	Orphan	Paediatric Age	Variations	PIP
		anaphylaxis. Treatment is indicated for adults and children with a body weight ≥ 30 kg.				
isavuconazole	J02AC05	**CRESEMBA** powder is indicated in patients from 1 year of age and older for the treatment of • invasive aspergillosis • mucormycosis in patients for whom amphotericin B is inappropriate **CRESEMBA** hard capsules are indicated in adults and in paediatric patients from 6 years of age for the treatment of • invasive aspergillosis • mucormycosis in patients for whom amphotericin B is inappropriate	YES	> 1 year	27/06/24 (22/08/24): Extension application to add a new strength of 40 mg hard capsule to be used in paediatric patients 6 years and older grouped with a type II variation (C.I.6.a) in order to extend the indication to include treatment of paediatric patients aged 1 year and older for Cresemba 200 mg powder	YES
ustekinumab	L04AC05	Paediatric plaque psoriasis **STEQEYMA** 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.	NO	> 6 years		NO
Nilotinib *(Generic)*	L01EA03	**Nilotinib Accord** 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.	NO	> 2 years		NO
smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	J07BX	**Imvanex**: Active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in individuals 12 years of age and older	NO	> 12 years	19/09/24 (19/09/24): Extension of indication to include active immunisation of adolescents from 12 to 17 years of age for IMVANEX.	YES
odevixibat	A05AX05	**KAYFANDA** is indicated for the treatment of cholestatic pruritus in Alagille syndrome (ALGS) in patients aged 6 months or older	NO	> 6 months		YES
Ustekinuma *(Biosimilar)*	L04AC05	Paediatric plaque psoriasis **Eksunbi** 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	NO	> 6 years		NO
Ustekinumab *(Biosimilar)*	L04AC05	Paediatric plaque psoriasis **Otulfi** is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, and who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies	NO	> 6 years		NO
Ustekinumab *(Generic)*	L04AC05	Paediatric plaque psoriasis **Fymskina** is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, and who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	NO	> 6 years		NO
spesolimab	L04AC22	**Spevigo** is indicated for the treatment of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age as monotherapy. **Spevigo** is indicated for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age.	NO	> 12 years	25/07/24 (25/09/24): Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (150 mg) and new route of administration (subcutaneous use), for the prevention of generalised pustular psoriasis (GPP)	YES

Active substance	ATC code	Paediatric indication	Orphan	Paediatric Age	Variations	PIP
					flares in adults and adolescents from 12 years of age.	
apremilast	L04AA32	Paediatric psoriasis **Otezla** is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years and weighing at least 20 kg who are candidates for systemic therapy.	NO	> 6 years weighing at least 20 kg	19/09/24 (21/10/24): Extension of indication to include the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years and weighing at least 20 kg who are candidates for systemic therapy,	YES
polihexanide	S01AX24	**AKANTIOR** is indicated for the treatment of Acanthamoeba keratitis in adults and children from 12 years of age.	YES	> 12 years		NO
zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	J07BB02	Active immunisation against H5N1 subtype of Influenza A virus in individuals 6 months of age and above. **AFLUNOV** should be used in accordance with official recommendations.	NO	> 6 months	19/09/24 (21/10/24): Extension of indication to include treatment of individuals 6 months of age and older for AFLUNOV	YES
empagliflozin metformin	A10BD20	**Synjardy** is indicated in adults and children aged 10 years and above for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise: □ in patients insufficiently controlled on their maximally tolerated dose of metformin alone in combination with other medicinal products for the treatment of diabetes, □ in patients insufficiently controlled with metformin and these medicinal products □ in patients already being treated with the combination of empagliflozin and metformin as separate tablets.	NO	> 10 years	19/09/24 (04/11/24): Extension of indication to include the treatment of children aged 10 years and above with type 2 diabetes for Synjardy	NO
Macitentan	C02KX04	Paediatric population **Opsumit**, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged less than 18 years and bodyweight ≥ 40 kg with WHO Functional Class (FC) II to III. **Opsumit**, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 2 years to less than 18 years with WHO Functional Class (FC) II to III	NO	> 2 years	25/07/24 (19/09/24): Extension application to introduce a new pharmaceutical form associated with a new strength (2.5 mg dispersible tablet) grouped with an extension of indication (C.I.6.a) to include, as monotherapy or in combination, the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 2 years to less than 18 years of age of WHO Functional Class (FC) II to III for OPSUMIT	YES
influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	J07BB02	Prophylaxis of influenza in adults and children from 2 years of age. **Flucelvax** should be used in accordance with official recommendations.	NO	> 2 years		YES
lutetium (177Lu) chloride	V10X	**Theralugand** is a radiopharmaceutical precursor, and it is not intended for direct use in patients. It is to be used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with lutetium (177Lu) chloride.	NO	children		NO
Meningococcal groups A, C, W, Y conjugate and group B vaccine	J07AH11	**Penbraya** is indicated for active immunisation of individuals 10 years of age and older to prevent invasive disease caused by Neisseria meningitidis groups A, B, C, W, and Y.	NO	> 10 years		YES

Active substance	ATC code	Paediatric indication	Orphan	Paediatric Age	Variations	PIP
(recombinant, adsorbed)						
bulevirtide	J05A	**Hepcludex** is indicated for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult and paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease.	YES	> 3 years	17/10/24 (25/11/24): Extension of indication to include treatment of chronic hepatitis delta virus (HDV) infection in paediatric patients 3 years of age and older weighing at least 10 kg with compensated liver disease for Hepcludex,	YES
Ustekinumab *(Biosimilar)*	L04AC05	Paediatric plaque psoriasis **ABSIMKY** 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.	NO	> 6 years		NO
marstacimab	B02BX11	**Hympavzi** is indicated for routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with: - severe haemophilia A (congenital factor VIII deficiency, FVIII < 1%) without factor VIII inhibitors, or - severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors.	NO	> 12 years weighing 35 kg		YES
Ustekinumab *(Biosimilar)*	L04AC05	Paediatric plaque psoriasis **IMULDOSA** 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.	NO	> 6 years		NO

6. References

1. European Parliament and Council Regulation (EC) No 1901/2006, 12 December 2006, on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

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3. Ceci A, Felisi M, Baiardi P, Bonifazi F, Catapano M, Giaquinto C, Nicolosi A, Sturkenboom M, Neubert A, Wong I. Medicines for children licensed by the European Medicines Agency (EMEA): the balance after 10 years Eur J Clin Pharmacol 2006. Nov;62(11):947-52.

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