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Human Medicines Development and Evaluation

Inventory of paediatric therapeutic needs

Infectious diseases

Agreed by PDCO	November 2012
Adopted by PDCO for release for consultation	7 December 2012
Start of public consultation	15 May 2013
End of consultation (deadline for comments)	26 July 2013 ¹
Agreed by PDCO	11 October 2013
Adoption by PDCO for final release	11 October 2013

Objective of the list

Based on Article 43 of the European Union [Paediatric Regulation](#) the Paediatric Committee at the European Medicines Agency (PDCO) is working to establish an inventory to identify the needs in the different therapeutic areas where there should be research and development of medicinal products for children. The inventory is based on the results of a [survey](#) of all paediatric uses of medicines in Europe and on the existing list of paediatric needs established by the former Paediatric Working Party; it will be published progressively by therapeutic area. Further information can be found on the [EMA website](#).

Disclaimer

The lists should not be viewed as a prescription tool nor as recommendations for treatment.

The authorisation status of the medicinal products as well as on available formulation(s) was taken into account, however, this information is limited and not available for all European Member States. Users of this list are therefore advised to check the authorisation status of the medicinal products of interest.

The methodology used to establish the list was based as much as possible on existing evidence. It is, however, acknowledged that identification of needs for research into medicinal products for paediatric use is partly based on subjective criteria and may change over time and according to region. This may

¹ The public consultation phase has been extended.



also be the case should further information of which the PDCO is not aware become available (e.g. on pharmacokinetics, safety and efficacy, submission of Paediatric Investigation Plans on listed products, etc.).

Notes

For the designation of the products International Non-proprietary Names (INN) are used whenever possible. Products are listed in alphabetical order within the product classes, not in any order of priority.

If not stated otherwise, the needs concern all paediatric age-groups.

The shaded products represent those where a positive decision has been adopted on a Paediatric Investigation Plan (PIP). For further information please consult the [EMA website](#).

1. Antibacterial Medicines

Product	Needs
Antibacterial medicines	
Penicillins	
Ampicillin, amoxicillin and cloxacillin	For treatment of various bacterial infections: <ul style="list-style-type: none"> Data on PK, dosing, age-appropriate palatable formulation for ampicillin and cloxacillin
Flucloxacillin	For prevention of respiratory infection in cystic fibrosis patients identified by neonatal screening, neuromuscular disorders, non-cystic fibrosis, bronchiectasis, immune deficiency: <ul style="list-style-type: none"> Data on PK, efficacy and safety Data on PK and dosing; age-appropriate palatable formulation for children aged less than 12 years
Cephalosporins	
Cephalosporins	For treatment of <i>Methicillin-resistant Staphylococcus aureus</i> (MRSA) infections: <ul style="list-style-type: none"> Data on efficacy, and, where needed, on PK and safety
Cefaclor	For treatment of various bacterial infections: <ul style="list-style-type: none"> Data on safety and efficacy in children aged less than one month
Cefixime	For treatment of various bacterial infections: <ul style="list-style-type: none"> Data on safety and efficacy in children aged less than 6 months
Cefuroxime	For treatment of various bacterial infections: <ul style="list-style-type: none"> Data on PK, dosing, safety in children aged less than 3 months
Carbapenems	
Meropenem	PIP agreed for 'Treatment of bacterial sepsis' and 'Treatment of bacterial meningitis'
Ertapenem	For treatment of various bacterial infections: <ul style="list-style-type: none"> Data on PK, dosing and safety in children aged less than 3 months

Product	Needs
Sulfonamides and Trimethoprim	
Sulfomethoxazole / trimethoprim	For treatment of <i>Methicillin-resistant Staphylococcus aureus</i> (MRSA) infections: <ul style="list-style-type: none"> • Data on PK and efficacy
Macrolides, Lincosamides and Streptogramins	
Clarithromycin	For treatment of various bacterial infections: <ul style="list-style-type: none"> • Data on PK, safety and efficacy in children aged less than 6 months • Data on PK, safety and efficacy for intravenous use in children aged less than 12 years For treatment of community acquired pneumonia (CAP): <ul style="list-style-type: none"> • Data on safety and efficacy in children aged less than 3 years
Clindamycin	For treatment of osteomyelitis, infections caused by <i>Methicillin resistant Staphylococcus aureus</i> (MRSA) and <i>Methicillin resistant Staphylococcus epidermidis</i> (MRSE): <ul style="list-style-type: none"> • Data on PK; relevant tissue and fluid levels; short-and long-term efficacy and safety; age-appropriate oral formulation
Erythromycin	For treatment of <i>Ureaplasma spp.</i> infection: <ul style="list-style-type: none"> • Data on PK, efficacy and safety in neonates
Aminoglycoside antibacterials	
Amikacin	PIP agreed for 'Treatment of <i>Pseudomonas aeruginosa</i> lung infection/colonisation in cystic fibrosis patients'
Tobramycin	PIP agreed for 'Treatment of <i>Pseudomonas aeruginosa</i> pulmonary infection/colonisation in patients with cystic fibrosis'
Quinolone antibacterials	
Ciprofloxacin	For treatment of infection in cystic fibrosis and complicated urinary tract infection: <ul style="list-style-type: none"> • Data on PK and safety in children aged less than 12 years

Product	Needs
Other antibacterials	
Colistimethate sodium	PIP agreed for 'Treatment of <i>Pseudomonas aeruginosa</i> pulmonary infection/colonisation in patients with cystic fibrosis'
Vancomycin	For treatment of various bacterial infections: <ul style="list-style-type: none"> • Data on PK/PD dosing, safety and efficacy in preterm and term neonates and infants. Age-appropriate formulation
Antituberculous Medicines	
Isoniazid (H) Rifampicin (R) Ethambutol (E) Pyrazinamide (Z)	For treatment of tuberculosis: <ul style="list-style-type: none"> • Data on PK, dosing, age-appropriate fixed dose combinations: HRZE, HRZ, HR

2. Antimycotic Medicines

Product	Needs
Amphotericin B	For treatment of various mycotic infections: <ul style="list-style-type: none"> Data on PK, safety and efficacy in children aged less than 1 month
Anidulafungin	PIP agreed for 'Treatment of invasive aspergillosis'
Caspofungin	PIP agreed for 'Treatment of fungal infections'
Griseofulvin	For treatment of various mycotic infections: <ul style="list-style-type: none"> Data on PK, safety, and efficacy in children aged less than 5 years of age; age-appropriate formulation
Itraconazole	For treatment of oral oesophageal candidosis in immunocompromised patients and for prevention of deep fungal infections: <ul style="list-style-type: none"> Data on PK, efficacy, safety and palatable age-appropriate formulation for children aged less than 12 years
Ketoconazole	For treatment of various mycotic infections: <ul style="list-style-type: none"> Data on PK, safety and dosing in children below 15 kg body weight; age-appropriate formulation
Posaconazole	For treatment of various mycotic infections: <ul style="list-style-type: none"> Data on PK, efficacy and safety
Voriconazole	PIP agreed for <ul style="list-style-type: none"> - Treatment of invasive aspergillosis - Prevention of invasive fungal infections'

3. Antiparasitic Medicines

Product	Needs
Anthelmintic medicines	
Albendazole	For treatment of various systemic helminthic infections: Data on PK and safety in children aged less than 6 years; age-appropriate formulation
Praziquantel	For treatment of neurocysticercosis: Data on PK and age-appropriate formulation in children aged less than 6 years
Intestinal anthelmintic medicines	
Mebendazole	For treatment of <i>Enterobius vermicularis</i> infection: Data on PK and safety in children aged less than 2 years
Antischistosomal and other antitrepatode medicines	
Praziquantel	For treatment of Trematode infections and neurocysticercosis Data on PK, dosing, safety and efficacy; age-appropriate formulation
Triclabendazole*	For treatment of liver (<i>Fasciola hepatica</i>) and lung flukes (<i>Paragonimus Westermanni</i>): Data on PK and safety in children aged less than 6 years; age-appropriate formulation
Antifilarial medicines	
Diethylcarbamazine	For treatment of <i>Oncocerca volvulus</i> infection (River blindness): <ul style="list-style-type: none"> • Data on PK, dosing, safety and efficacy; age-appropriate formulation
Ivermectin	For treatment of lymphatic filariasis and scabies: <ul style="list-style-type: none"> • Data on PK, dosing, safety in children aged less than 5 years or less than 15kg; age-appropriate formulation

Antileishmaniasis medicines	
Miltefosine	For treatment of leishmaniasis: <ul style="list-style-type: none"> Data on PK and dosing in children below 9kg body weight; age-appropriate formulation
Antitrypanosomal medicines	
Benznidazole	For treatment of American trypanosomiasis (Chagas disease, <i>Trypanosoma cruzi</i>): <ul style="list-style-type: none"> Data on PK, dosing, safety and efficacy; age-appropriate formulation
Eflornithine	For treatment of African sleeping sickness (<i>Trypanosoma brucei</i>): <ul style="list-style-type: none"> Data on PK, dosing, safety and efficacy in children aged less than 12 years; age-appropriate formulation
Nifurtimox*	For treatment of congenital Chagas disease (<i>Trypanosoma cruzi</i>): <ul style="list-style-type: none"> Data on PK in children aged less than 1 year of age; age-appropriate formulation
Antimalarial medicines	
Artemether / lumefantrine	PIP agreed for 'Treatment of <i>Plasmodium falciparum</i> malaria'
Dihydroartemisinin / Piperaquine phosphate	PIP agreed for 'Treatment of uncomplicated malaria caused by <i>Plasmodium falciparum</i> '
Mefloquine	For therapy and prevention of malaria: <ul style="list-style-type: none"> Data on PK for children with less than 5 kg body weight; age-appropriate formulation
Proguanil (combinations)	For therapy and prevention of malaria: <p>Proguanil/chloroquine</p> <ul style="list-style-type: none"> Data on PK, dosing in children below 1 year of age; age-appropriate formulation <p>Proguanil/atovaquon:</p> <ul style="list-style-type: none"> Data on PK, dosing in children below 11kg body weight; age-appropriate formulation

4. Antiviral Medicines

Product	Needs
Herpes Virus, Cytomegaly Virus (CMV)	
Brivudine	For treatment of herpes simplex virus infection: <ul style="list-style-type: none"> Data on PK, efficacy and safety; age appropriate formulation
Cidofovir	For treatment of cytomegalovirus retinitis in acquired immunodeficiency: <ul style="list-style-type: none"> Data on PK, efficacy and safety
Famciclovir	Treatment of herpes virus infections: <ul style="list-style-type: none"> Data on PK, efficacy and safety; age-appropriate formulation
Foscarnet	For treatment of CMV and herpes simplex virus infection: <ul style="list-style-type: none"> Data on PK, efficacy and safety
Ganciclovir	Treatment of cytomegalovirus (CMV) infection: <ul style="list-style-type: none"> Data on PK, efficacy and safety (including long-term safety); age-appropriate oral formulation.
Maribavir	PIP agreed for 'Prevention of CMV disease'
Valaciclovir	Treatment of herpes virus infections: <ul style="list-style-type: none"> Data on PK, efficacy and safety for children aged below 12 years; age-appropriate formulation
Valganciclovir	PIP agreed for 'Prevention of infection due to cytomegalovirus in solid organ transplant recipients'
Hepatitis Virus and other	
Amantadine	For prevention and treatment of influenza A: <ul style="list-style-type: none"> Data on efficacy and safety in children aged less than 2 years; age appropriate formulation
Boceprevir	PIP agreed for 'Treatment of chronic hepatitis C'.
Entecavir	PIP agreed for 'Treatment of chronic hepatitis B'.

Product	Needs
Interferon alfa-2a	For treatment of hepatitis B and hepatitis C: <ul style="list-style-type: none"> Data on PK, efficacy and safety; age-appropriate formulation
Interferon alfacon-1	For treatment of chronic viral hepatitis C: <ul style="list-style-type: none"> Data on PK, efficacy and safety; age-appropriate formulation
Lamivudine	For treatment of chronic hepatitis B <ul style="list-style-type: none"> Data on PK, efficacy and safety
Oseltamivir	PIP agreed for 'Treatment and prevention of influenza'.
Peginterferon alfa-2a	PIP agreed for <ul style="list-style-type: none"> - Treatment of chronic hepatitis C - Treatment of chronic hepatitis B'.
Peginterferon alfa-2b	PIP agreed for 'Treatment of chronic viral hepatitis C'.
Ribavirine	PIP agreed for 'Treatment of chronic viral hepatitis C'.
Simeprevir	PIP agreed for 'Treatment of chronic viral hepatitis C'.
Human Immunodeficiency Virus (HIV-1)	
Abacavir	For treatment of human immunodeficiency virus (HIV-1) infection: <ul style="list-style-type: none"> Data on PK, efficacy and safety in children aged less than 3 months
Atazanavir	PIP agreed for 'Treatment of human immunodeficiency virus (HIV-1) infection'.
Cobicistat	PIP agreed for 'Treatment of human immunodeficiency virus (HIV-1) infection'.
Darunavir	PIP agreed for 'Treatment of human immunodeficiency virus infection'.
Didanosine	For treatment of human immunodeficiency virus (HIV-1) infection: <ul style="list-style-type: none"> Data on PK, efficacy and safety in children aged less than 3 months

Product	Needs
Dolutegravir / abacavir / lamivudine	PIP agreed for 'Treatment of human immunodeficiency virus (HIV-1) infection'.
Efavirenz	For treatment of human immunodeficiency virus (HIV-1) infection: <ul style="list-style-type: none"> Data on PK, efficacy and safety in children aged less than 3 years
Elvitegravir	PIP agreed for 'Treatment of human immunodeficiency virus (HIV-1) infection'.
Elvitegravir / emtricitabine / tenofovir disoproxil (as fumarate) / cobicistat	PIP agreed for 'Treatment of human immunodeficiency virus (HIV-1) infection'.
Emtricitabine	For treatment of human immunodeficiency virus (HIV-1) infection: <ul style="list-style-type: none"> Data on efficacy and safety in children aged less than 4 months
Etravirine	PIP agreed for 'Treatment of human immunodeficiency virus infection'.
Lopinavir	For treatment of human immunodeficiency virus (HIV-1) infection: <ul style="list-style-type: none"> Data on PK, safety and efficacy in children aged less than 2 years; age-appropriate formulation
Lopinavir /ritonavir	PIP agreed for 'Treatment of human immunodeficiency virus (HIV-1) infection'.
Maraviroc	PIP agreed for 'Treatment of human immunodeficiency virus infection'.
Nevirapine	PIP agreed for 'Treatment of Human immunodeficiency virus (HIV-1) infection'.
Raltegravir	PIP agreed for 'Treatment of human immunodeficiency virus (HIV-1) infection'.
Rilpivirine	PIP agreed for 'Treatment of Human Immunodeficiency Virus (HIV-1) infection in ARV-naïve patients'.
Tenofovir	PIP agreed for <ul style="list-style-type: none"> '-Treatment of human immunodeficiency virus (HIV) disease resulting in other conditions -Treatment of chronic viral hepatitis B'
Tenofovir / emtricitabine / rilpivirine	PIP agreed for 'Treatment of human immunodeficiency virus (HIV-1) infection'.

Product	Needs
Vicriviroc	PIP agreed for 'Treatment of human immunodeficiency virus infection'.