



**ASSESSMENT OF THE PAEDIATRIC NEEDS
ANTIINFECTIOUS THERAPY WITH FOCUS ON ANTIMYCOTICS, ANTIVIRALS (EXCEPT HIV)**

DISCLAIMER

The Paediatric Working Party (PEG) is working to identify the needs in the different therapeutic areas where there should be research and development of medicinal products for children, either old (i.e. off patent) or new ones (including those under development). Products on the list are not in any order of priority.

The lists should not be viewed as a prescription tool nor as recommendations for treatment. Accuracy of data including in particular authorised doses cannot be guaranteed.

Information on existing marketing authorisations is very limited and therefore information under “authorised” includes the indication in broad term (only related to chemotherapy), the lower age group authorised in at least one Member State, the authorised dose(s) (if authorised for use in patients less than 18 years of age) and formulation(s) in at least in one Member State.

Please refer to the EMEA/PEG procedure for identifying the paediatric needs for further information.

Comments from third parties are expected especially to complete and or update the list as necessary.

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END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 May 2007

Comments should be provided to: peg@emea.europa.eu or by fax +44 20 7523 7040 using the following [template](#).

If not stated separately, the need for availability in all Member States of the Community applies to all medicinal products included in this list.

ANTIMYCOTICS

ITRACONAZOLE

<i>Authorised indication</i>	Treatment of oral and/or oesophageal candidosis in HIV-positive or other immunocompromised patients
<i>Authorised age group</i>	>18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Solution for i.v. infusion, capsules, oral solution
<i>Needs</i>	PK, efficacy and safety data < 18 years

AMPHOTERICIN B

<i>Authorised indication</i>	Severe systemic and/or deep mycoses such as coccidioidomycosis, cryptococcosis, candidosis, histoplasmosis, leishmaniasis, blastomycosis; Treatment of suspected mycosis in neutropenic febrile patients: Prevention of candidosis
<i>Authorised age group</i>	Suspension: Children > 1 month (intestinal candidiasis), Neonates: prophylaxis i.v. formulation: Children: age limit not specified Lipid formulation: Children: age limit not specified
<i>Authorised dose</i>	0.25mg/kg of body weight gradually increasing to a level of 1.0mg/kg of body weight depending on individual response and tolerance (<i>Fungizone</i>) 1.0 mg/kg of body weight, increased stepwise to 3.0 mg/kg (<i>Ambisone</i>)
<i>Authorised formulation</i>	Fungizone: Oral suspension 10% for children, infants; capsule, liposomal forms, suspension for injection
<i>Needs</i>	Define lower age limit based on data on efficacy and safety and investigate where needed. Full Development needed in neonates

VORICONAZOLE

<i>Authorised indication</i>	Invasive aspergillosis, candidaemia in non-neutropenic patients, fluconazole-resistant serious invasive <i>Candida</i> infections (including <i>C. krusei</i>), serious fungal infections caused by <i>Scedosporium</i> spp. and <i>Fusarium</i> spp.
<i>Authorised age group</i>	> 2 years
<i>Authorised dose</i>	i.v. 7 mg/kg twice daily; oral 200mg (5 ml) twice daily
<i>Authorised formulation</i>	50 mg and 200 mg film-coated tablets, 200 mg powder for solution for infusion, 40 mg/ml powder for oral suspension
<i>Needs</i>	Data on PK, efficacy and safety < 2 years

FLUCONAZOLE

<i>Authorised indication</i>	Candidosis, cryptococcal meningitis and other cryptococcal infections (skin, lung), candida prophylaxis and treatment in immunocompromised patients
<i>Authorised age group</i>	> 4 weeks
<i>Authorised dose</i>	3mg/kg daily
<i>Authorised formulation</i>	Capsules 50, 100, 150mg, solution for i.v. infusion 2mg/mL, powder for oral suspension 10, 40, 50, 200mg
<i>Needs</i>	Data on PK, efficacy and safety < 4 weeks

POSACONAZOLE

<i>Authorised indication</i>	Treatment of the following invasive fungal infections in adults: - Invasive aspergillosis in patients with disease that is refractory to amphotericin B or
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	<p>itraconazole or in patients who are intolerant of these medicinal products;</p> <ul style="list-style-type: none"> - Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B; - Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; - Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products. <p>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.</p>
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Oral suspension
<i>Needs</i>	Data on PK, efficacy and safety <18 years
CASPOFUNGIN	
<i>Authorised indication</i>	Invasive candidiasis, invasive aspergillosis refractory to or intolerant of amphotericin B, lipid formulations of amphotericin B and/or itraconazole. Empirical therapy for presumed fungal infections (such as <i>Candida</i> or <i>Aspergillus</i>) in febrile, neutropenic adult patients
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Powder for reconstitution for infusion
<i>Needs</i>	Data on PK, efficacy and safety < 18 years Age appropriate formulation
ANTI VIRALS (HERPES VIRUS, CYTOMEGALY VIRUS)	
FAMCICLOVIR	
<i>Authorised indication</i>	Acute herpes zoster infections, herpes zoster and herpes simplex infections in immunocompromised patients, treatment of genital herpes and prevention of recurrent genital herpes infections. Reduction of duration of postherpetic neuralgia
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Tablets 500, 250, 125mg
<i>Needs</i>	Data on PK, efficacy and safety < 18 years Age appropriate formulation
GANCICLOVIR	
<i>Authorised indication</i>	Severe CMV infection
<i>Authorised age group</i>	>18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
<i>Needs</i>	Data on PK, efficacy and safety (including long-term safety) <18 years
VALACICLOVIR	
<i>Authorised indication</i>	Treatment of herpes zoster infections, treatment of herpes simplex (HSV-1 and HSV-2) infections, prevention of recurrent herpes simplex infections, Prevention of post-transplant cytomegaly virus infection
<i>Authorised age group</i>	> 12 years (<i>France</i>)
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Tablets 250mg, 500mg

<i>Needs</i>	Data on PK, efficacy and safety < 18 years Age appropriate formulation
VALGANCICLOVIR	
<i>Authorised indication</i>	CMV treatment and prophylaxis
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Injection solution 500mg
<i>Needs</i>	Data on PK, efficacy and safety < 18 years Age appropriate formulation Availability in all Member States
CIDOFOVIR	
<i>Authorised indication</i>	CMV retinitis in aquired immunodeficiency
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	5 mg/kg i.v. infusion once daily for 14 days
<i>Authorised formulation</i>	Infusion solution
<i>Needs</i>	PK, efficacy and safety <18 years
FOSCARNET	
<i>Authorised indication</i>	Severe CMV and HSV infection
<i>Authorised age group</i>	Adults (<i>France, United Kingdom, Germany</i>)
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Solution for infusion
<i>Needs</i>	Data on PK, efficacy and safety <18 yrs
BRIVUDINE	
<i>Authorised indication</i>	Severe HSV infection
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	125 mg
<i>Authorised formulation</i>	Tablets
<i>Needs</i>	Data on PK, efficacy and safety <18 years Availability in all Member States
ANTI VIRALS (HEPATITIS AND OTHER)	
LAMIVUDINE	
<i>Authorised indication</i>	Chronic hepatitis B
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	
<i>Authorised formulation</i>	Film coated tablets, 100mg, oral solution 10mg/ml
<i>Needs</i>	Data on PK, efficacy and safety < 18 years
RIBAVIRINE	
<i>Authorised indication</i>	In combination with interferon for chronic hepatitis C
<i>Authorised age group</i>	> 3 years (in combination with interferons alpha 2b)
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Capsules, oral solution
<i>Needs</i>	Data on efficacy and safety (including long-term safety) < 3 years
AMANTADINE	
<i>Authorised indication</i>	Prophyaxis and treatment of influenza A
<i>Authorised age group</i>	> 2 years (<i>Finland</i>)

<i>Authorised dose</i>	50-200mg depending on age
<i>Authorised formulation</i>	Capsules 100mg, Tablets 100mg
<i>Needs</i>	Data on efficacy and safety < 2 years
OSELTAMIVIR	
<i>Authorised indication</i>	Treatment and prevention of influenza A and B
<i>Authorised age group</i>	> 1 year
<i>Authorised dose</i>	Treatment: Children > 1 years: 75 mg twice daily for 5 days Prevention: Children > 1 years: 75 mg once daily for 10 days
<i>Authorised formulation</i>	75 mg capsules, oral solution
<i>Needs</i>	PK, efficacy and safety < 1 year
INTERFERON ALFA 2a	
<i>Authorised indication</i>	Hepatitis B and C
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Prefilled syringe containing solution for injection 18MIU/0.6mL
<i>Needs</i>	PK, efficacy and safety < 18 years Age appropriate formulation (without benzylalcohol)
PEGINTERFERON ALFA 2a	
<i>Authorised indication</i>	Hepatitis B and C
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Solution for injection 135, 180 µg/0.5 mL
<i>Needs</i>	PK, efficacy and safety < 18 years Age appropriate formulation
INTERFERON ALFA 2b	
<i>Authorised indication</i>	Hepatitis C (children)
<i>Authorised age group</i>	> 3 years
<i>Authorised dose</i>	3 Mio IU (in combination with ribavirin)
<i>Authorised formulation</i>	Solution for injection
<i>Needs</i>	Age appropriate formulation in all Member States
PEGINTERFERON ALFA 2b	
<i>Authorised indication</i>	Hepatitis C
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Powder for solution for injection
<i>Needs</i>	PK, efficacy and safety < 18 years Age appropriate formulation
INTERFERON Alfacon-1	
<i>Authorised indication</i>	Chronic hepatitis C
<i>Authorised age group</i>	> 18 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Solution for injection 9 µg/ 0.3 ml (9µg = 9 MioUnits)

<i>Needs</i>	PK, efficacy and safety < 18 years Age appropriate formulation
INTERFERON Beta-1	
<i>Authorised indication</i>	Multiple sclerosis
<i>Authorised age group</i>	> 16 years
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Solution for injection 22, 44 µg/0.5 mL
<i>Needs</i>	PK, efficacy and safety < 16 years Age appropriate formulation

The PEG considers that there is no need for additional data for the following products:

ACICLOVIR