European Medicines Agency
Evaluation of Medicines for Human Use

London, 02 June 2006
Doc. Ref. EMEA/224696/2006

ASSESSMENT OF THE PAEDIATRIC NEEDS CHEMOTHERAPY PRODUCTS (PART II) - SUPPORTIVE THERAPY -

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.

AGREED BY PAEDIATRIC WORKING PARTY (PEG)	2 June 2006
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	29 June 2006
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 December 2006

Comments should be provided using this template to PEG Secretariat: peg@emea.europa.eu
Fax +44 20 7523 7040.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel: (44-20) 74 18 84 00, Fax: (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

GROWTH FACTORS	
EPOETIN ALFA	
Authorised indication	Paediatric indication: anaemia in chronic renal disease Not authorised for tumour indications in children (Adult indications: renal anemia and treatment of symptomatic anaemia in adult patients with solid tumours receiving chemotherapy)
Authorised age group	-
Authorised dose	No authorised dosing recommendations exist in children for indications related to oncology Doses for renal disease: Generally, children under 30 kg require higher maintenance doses than children over 30 kg and adults
Authorised formulation	Renal anaemia: only IV injection
Needs	Extension of indication to treatment of symptomatic anaemia in children with tumours receiving chemotherapy Data on PK, efficacy and safety
EPOETIN BETA	
Authorised indication	Paediatric indication: anaemia in chronic renal failure; prevention of anemia in prematures, Not authorised for tumour indications in children (Adult indications: renal anemia and treatment of symptomatic anaemia in adult patients with solid tumours receiving chemotherapy)
Authorised age group	-
Authorised dose	No authorised dosing recommendations exist in children for indications related to oncology (renal failure: Results of clinical studies in children have shown that, on average, the younger the patients, the higher the doses required. 250 IU/kg, 3 times a week for 6 weeks for prevention of anemia in prematures)
Authorised formulation	SC or IV injection (in children s.c. injection is not recommended)
Needs	Extension of indication to treatment of symptomatic anaemia in children with tumours receiving chemotherapy Data on PK, efficacy and safety upgrade to adult indication: data on PK, efficacy and safety; Age appropriate strength (prematures, cancer related indications)
DARBEPOETIN ALFA	
Authorised indication	Anemia associated with chronic renal failure (Adult indications also symptomatic anemia in chemotherapy patients)
Authorised age group	> 11 years for chronic renal failure
Authorised dose	450 ng/kg once weekly
Authorised formulation	Solution for injection s.c. or i.v. prefilled syringes in dose strength from 10 to 500 micrograms
Needs	Extension of indication to treatment of anaemia and reduction of red cell transfusion need in children treated for cancer or BMT. PK, efficacy and safety in all paediatric age groups
LENOGRASTIM	
Authorised indication	Bone marrow transplantation, myelosuppressive cytotoxic chemotherapy
Authorised age group	2 – 18 years in BMT
Authorised dose	150 micrograms/m2
Authorised formulation	for IV infusion
Needs	PK, efficacy and safety in children < 2 years
FILGRASTIM	

Authorised indication	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy, Severe congenital, cyclic, or idiopathic neutropenia, Treatment of persistent neutropenia (ANC less than or equal to 1.0 x109/l) in patients with advanced HIV infection
Authorised age group	Children
Authorised dose	0.5 MU (5 µg)/kg/day. The dosage recommendations in paediatric patients are the same as those in adults receiving myelosuppressive cytotoxic chemotherapy
Authorised formulation	SC injection and for IV infusion
Needs	Define lower age limit Age appropriate strength
PEGFILGRASTIM	
Authorised indication	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).
Authorised age group	No age limit specified
Authorised dose	-
Authorised formulation	SC injection
Needs	PK, efficacy and safety in paediatric age groups (> 2 years)
PALMIFERIN (KERATINOCYTE DERIVED GROWTH FACTOR)	
Authorised indication	Prevention of mucositis after autologous bone marrow transplantation
Authorised age group	> 18 years
Authorised dose	-
Authorised formulation	Solution for i.v. infusion
Needs	Full development for extension of indication to mucositis. PK, efficacy and safety data in all paediatric age groups
ANTIEMETICS	
ONDANSETRON	
Authorised indication	Prevention of cancer chemotherapy induced nausea
Authorised age group	> 2 years (F); (no lower age limit in UK)
Authorised dose	i.v. 5 mg/m2 , p.o 4 mg for children 10 -25 kg and 8 mg for children >25mg; >15 years as adults.
Authorised formulation	Film-coated tablets, oral lyophilisate, syrup 4 mg/5 ml; solution for IV injection UK also “Melts” 4mg, NO suppositories 16 mg (adults).
Needs	Development of rectal appropriate formulations in appropriate strength, PK, bioavailability, efficacy and safety for children under 2 years. Availability in all Member States
TROPISETRON	
Authorised indication	Prevention of cancer chemotherapy induced nausea
Authorised age group	> 2 years
Authorised dose	0,2 mg/kg/day (max. 5 mg) for children <25 kg i.v, for children >25mg p.o.
Authorised formulation	Capsules, solution for injections
Needs	PK, safety and efficacy in children < 2 years Age appropriate formulation Availability in all Member States
ANTITOXIC AGENTS	
UROMITEXAN	
Authorised indication	Prevention of urinary toxicity of cyclophosphamide and ifosfamide

Authorised age group	-
Authorised dose	-
Authorised formulation	Solution for injection for IV infusion, 400 mg tablets, 600 mg scored tablets
Needs	PK, efficacy and safety. (age limit according to age limit of cyclophophymide/ifosphamide)
AMIFOSTINE	
Authorised indication	Reduction of renal toxicity of cisplatin / reduction of the risk of neutropenic infections in the combination of cisplatin and cyclophosphamide, prevention of xerostomia during radiotherapy
Authorised age group	> 18 years
Authorised dose	-
Authorised formulation	Lyophilisate and solution IV infusion, 375, 500mg
Needs	PK, efficacy and safety Age appropriate formulation
PILOCARPINE	
Authorised indication	Prevention and treatment of xerostomia during radiotherapy
Authorised age group	> 18 years
Authorised dose	-
Authorised formulation	filmcoated tablets 5mg
Needs	PK, efficacy and safety Age appropriate formulation
OTHER	
RASBURICASE	
Authorised indication	Treatment of hyperuricaemia in patients with high tumor burden immediately before chemotherapy
Authorised age group	No age limit specified
Authorised dose	0.2 mg/kg/day, no specific dosing recommendations for children
Authorised formulation	Powder and solvent for solution for infusion
Needs	PK, efficacy and safety
ALLOPURINOL	
Authorised indication	Hyperuricemia. Use in children is rarely indicated, except in malignant conditions (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.
Authorised age group	No age limit
Authorised dose	20 mg/kg/day up to a maximum of 400 mg daily
Authorised formulation	Tablets 100, 300mg
Needs	Age appropriate formulation (liquid oral) Need for i.v. solution
UNMET MEDICAL NEEDS	
Name of the condition	Prophylaxis and treatment of veno-occlusive disease in children receiving haemopoietic stemcell transplantation
Needs	Ursodeoxycholic Acid, Defibrotide
Name of the condition	Chemotherapy induced osteoporosis, bone metastases
Needs	Biphosphonates
NO NEEDS: Medicinal products considered by the PEG to be devoid of interest to be developed in paediatric oncology indications or below the labelled age	
CYCLIZINE	
LEVOMEPROMAZINE	

METOCLOPRAMIDE
HALOPERIDOL
DOMPERIDONE
METOPIMAZINE
DOLASETRON
GRANISETRON
CALCIUM LEVOFOLINATE
CALCIUM FOLINATE