European Medicines Agency
Evaluation of Medicines for Human Use

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ASSESSMENT OF THE PAEDIATRIC NEEDS
ASTHMA AND OTHER OBSTRUCTIVE CHRONIC LUNG DISEASES

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, the lower age group authorised in at least one Member State, the authorised dose(s) and formulation(s) in at least in one Member State.

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

AGREED BY PAEDIATRIC WORKING PARTY (PEG)	20 October 2006
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	16 November 2006
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 May 2007

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

BETA 2-ADRENERGIC DRUGS	
SALBUTAMOL	
Authorised indication	Asthma, reversible pulmonary obstruction
Authorised age group	All age groups (oral solution not licensed in < 2years)
Authorised dose	0.25 to 0.5 mg per age via inhalation (aerosol/powder) Nebulised: 0.05-0.15 mg/kg x 4, oral: 1-4 mg (dep on age) x 3-4 Maximum 8 drops (4 mg)
Authorised formulation	Tablets, oral solution, aerosol for inhalation, powder for inhalation, solution for nebulisation, i.v. solution
Needs[1]	Data on pharmacokinetics (PK), efficacy and safety in bronchopulmonary dysplasia in the neonate
FENOTEROL	
Authorised indication	Acute asthma, reversible pulmonary obstruction, prevention of exercise induced obstruction
Authorised age group	> 4 years
Authorised dose	100 – 200 µg up to four times daily
Authorised formulation	Aerosol for inhalation, solution for nebulisation
Needs	Data on pharmacokinetics (PK), efficacy and safety in children < 4 years
TERBUTALIN	
Authorised indication	Acute asthma, acute pulmonary obstruction (obstructive bronchitis)
Authorised age group	All age groups
Authorised dose	Per os: 0.075 mg/kg, powder/aerosol: 0.25-0.5 mg, nebulised: 2.5-5 mg, i.v.: 25 µg/kg per 24h
Authorised formulation	Oral solution, aerosol for inhalation, solution for nebulisation, i.v. solution
Needs	Data on pharmacokinetics (PK), efficacy and safety in children < 6 months Data on long term safety
FORMOTEROL	
Authorised indication	Long-term bronchodilator therapy in reversible pulmonary obstruction
Authorised age group	> 5 years
Authorised dose	12 – 24 µg twice daily (Foradil)
Authorised formulation	Dry powder for inhalation
Needs	Data on PK efficacy and safety in children > 2 years Age appropriate formulation Long term safety
SALMETEROL	
Authorised indication	Long-term treatment of asthma in reversible pulmonary obstruction
Authorised age group	> 4 years

[1] The list will specify which kind of data would be needed but neither the design, nor the number of studies (e.g. PK, efficacy). The lists will indicate the need for 'age-appropriate' formulations, without specifying which one, to keep options open and room for innovation.

Authorised dose	50 – 100 µg twice daily
Authorised formulation	Powder for inhalation, aerosol for inhalation
Needs	Data on safety in long term use Data on safety with or without concomitant inhalation of glucocorticoids
ANTI-MUSCARINIC BRONCHODILATORS (PARASYMPATHICOLYTICS)	
TIOTROPIUM BROMIDE	
Authorised indication	Chronic obstructive pulmonary disease
Authorised age group	> 18 years
Authorised dose	18 µg (adults)
Authorised formulation	Powder for inhalation (adults)
Needs	Data on PK, efficacy and safety in children < 18 yrs Age appropriate formulation Data on safety in long term use
LEUKOTRIENE ANTAGONISTS	
MONTELUKAST	
Authorised indication	Treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom 'as-needed' short acting β-agonists provide inadequate clinical control of asthma. Alternative treatment option to low-dose inhaled corticosteroids for 2 to 5 year old patients with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids Prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction
Authorised age group	> 6 mo (add on therapy), > 2 yrs (monotherapy)
Authorised dose	4 mg once daily (6 mo - 6 yrs), 5 mg (6 - 15 yrs), 10 mg (15 - 18 yrs)
Authorised formulation	Chewable tablets, granules
Needs	Data on efficacy in monotherapy below 2 years Data on long term safety
ZAFIRLUKAST	
Authorised indication	Treatment of asthma
Authorised age group	> 12 years
Authorised dose	20mg twice daily
Authorised formulation	Tablets 20 mg
Needs	Data on efficacy, safety and dose in children < 12 years Efficacy in mono therapy Age appropriate formulation Long term safety
INHALED CORTICOSTEROIDS (ICS)	
General need for ICS: Long tern safety data, in particular on bone and lung	
BECLOMETHASON	
Authorised indication	Prophylaxis of asthma
Authorised age group	> 5 years

Authorised dose	50-100 µg twice daily
Authorised formulation	Aerosol for inhalation, powder for inhalation (> 6 years)
Needs	Data on efficacy, safety and dose in children < 5 years Age appropriate formulation Data on efficacy and safety in BPD
FLUTICASONE	
Authorised indication	Prophylaxis of asthma
Authorised age group	> 4 years (powder) (*Germany*) > 1 year (*Norway*) (aerosol)
Authorised dose	1-4 years: 100 µg twice daily (aerosol), 0.05 - 0.2 mg (4 - 16 years) , 0.5 mg (> 16 years) twice daily,
Authorised formulation	Aerosol for inhalation, powder for inhalation, solution for nebulisation
Needs	Data on efficacy, safety and dose in children < 1 year Age appropriate formulation Data on efficacy and safety in BPD
BUDESONIDE	
Authorised indication	Prophylaxis of asthma
Authorised age group	> 3 month (*Great Britain*) Nebulisation: All ages (*Norway)* (Aerosol: > 2 years, powder: > 6 years)
Authorised dose	500 – 1000 µg twice daily Nebulised : 0,25-0,5 mg x 1-2, up till 1 mg x 2, Aerosol/powder: 200-800 µg/day,
Authorised formulation	Aerosol for inhalation, powder for inhalation, solution for nebulisation
Needs	Data on efficacy, safety and dose in children < 3 month Age appropriate formulation Data on efficacy and safety in BPD
MOMETASONE	
Authorised indication	Prophylaxis of asthma
Authorised age group	> 12 years (*Great Britain*)
Authorised dose	200 – 400 µg twice daily
Authorised formulation	Powder for inhalation
Needs	Data on efficacy, safety and dose in children < 12 years Age appropriate formulation
CICLESONIDE	
Authorised indication	Prophylaxis of asthma
Authorised age group	>12 years (*Sweden*)
Authorised dose	80 – 160 µg, twice daily
Authorised formulation	Solution for inhalation
Needs	Data on PK (long acting), efficacy, safety and dose in children < 12 years Age appropriate formulation
COMBINATION THERAPY ICS AND LONG-ACTING BETA 2- AGONISTS	
SALMETEROL + FLUTICASONE	
Authorised indication	Prophylaxis of asthma
Authorised age group	> 4 years
Authorised dose	25/50 to 50/250 µg twice daily
Authorised formulation	Aerosol for inhalation, powder for inhalation

Needs	Data on efficacy, safety and dose in children < 4 years Data on safety in long-term use
FORMOTEROL + BUDESONIDE	
Authorised indication	Prophylaxis of asthma
Authorised age group	> 6 yrs
Authorised dose	80/4.5 to 320/9 µg twice daily
Authorised formulation	Dry powder inhalation
Needs	Data on efficacy, safety and dose in children < 6 years Data on safety in long-term use
UNMET MEDICAL NEEDS – SPECIAL CONSIDERATIONS	
Needs	There is a need for age-appropriate devices and delivery systems for administration to the bronchial system. Various drug delivery systems are offered (e.g. inhalers, spacers, nebulisers) and training is needed to use the devices appropriately. Disposition studies incl. data to link the delivered dose to the actual needed target concentration. Consistency in delivering dose per inhalation. Development / evaluation of patient leaflets. Treatment of severe obstruction

The following products are considered by the PEG to be devoid of interest:

SODIUM CHROMOGLICATE
NEDOCROMIL
IPATROPIUM BROMIDE