



29 April 2016  
EMA/244726/2016  
Human Medicines Research and Development Support

## Inventory of paediatric therapeutic needs

### Respiratory

Draft agreed by PDCO	April 2016
Adopted by PDCO for release for consultation	29 April 2016
Start of public consultation	11 May 2016
End of consultation (deadline for comments)	11 July 2016

Comments should be provided using this [template](#). The completed comments form should be sent to [paediatrics@ema.europa.eu](mailto:paediatrics@ema.europa.eu)

### 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 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 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 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 order of priority.

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

Products with an agreed Paediatric Investigation Plan (PIP) are not included in the list - for information on these products please consult the [EMA website](#).

Needs specific for the neonatal population (e.g. bronchopulmonary dysplasia) will be covered in a separate neonatal inventory.

Product	Needs
<b>Beta 2-adrenergic drugs</b>	
Formoterol	Data on PK, efficacy and safety in children >2 years of age in the treatment of asthma (as reliever medication)  Long-term safety
<b>Leukotriene antagonists</b>	
Montelukast	Data on PK, efficacy and safety in the treatment of severe bronchiolitis and post-bronchiolitis wheeze. Liquid formulation for the use in enteral tubes.
Zafirlukast	Data on PK, efficacy and safety in children <12 years of age in the treatment of asthma  Efficacy in monotherapy  Long-term safety
<b>Inhaled corticosteroids</b>	
Beclomethasone dipropionate	Data on PK, efficacy and safety in children <5 years of age in the treatment of asthma
Ciclesonide	Data on PK, efficacy and safety in children <12 years of age in the treatment of asthma
Fluticasone propionate	Data on PK, efficacy and safety in children < 4 years of age in the treatment of asthma
Mometasone furoate	Data on PK, efficacy and safety in children <12 years of age in the treatment of asthma

<b>Product</b>	<b>Needs</b>
<b>Intranasal corticosteroids</b>	
Fluticasone furoate	Data on PK, efficacy and safety in the treatment of allergic rhinitis and hypertrophic adenoids, particularly in children <6 years of age
Budesonide	Data on PK, efficacy and safety in the treatment of allergic rhinitis and hypertrophic adenoids, particularly in children <6 years of age
Ciclesonide	Data on PK, efficacy and safety in children in the treatment of allergic rhinitis
<b>Combination therapy inhaled corticosteroids and long-acting Beta 2-agonists</b>	
Formoterol + budesonide	Data on PK, efficacy and safety in children <6 years of age in the treatment of asthma Data on safety in long-term use
Salmeterol + fluticasone propionate	Data on PK, efficacy and safety in children <5 years of age in the treatment of asthma Data on safety in long-term use
<b>Mucolytics</b>	
Dornase alfa	Data on PK, efficacy and safety in the treatment of primary ciliary dyskinesia and non-cystic fibrosis bronchiectasis <5 years of age
<b>Proteinase Inhibitors</b>	
Alpha-1 antitrypsin inhibitor	Data on PK, efficacy and safety in the treatment of cystic fibrosis in all age groups
<b>Hyperosmolar agents</b>	
Hypertonic saline solution	Data on efficacy and safety in the treatment of primary ciliary dyskinesia and non-cystic fibrosis bronchiectasis in all age groups (except neonates) Data on efficacy and safety in the treatment of bronchiolitis
<b>Bronchodilators</b>	
Magnesium sulfate	Data on efficacy and safety in the treatment of severe exacerbations in acute asthma, either administered intravenously or nebulised

**General need:**

- Age-appropriate formulations.
- Age-appropriate devices and delivery systems (including spacers) for administration to the bronchial system and PK data to support dosing.