



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Research and Development Support

Inventory of paediatric therapeutic needs Ophthalmology

Adopted by PDCO for release for consultation	25 April 2014
Start of public consultation	9 May 2014
End of consultation (deadline for comments)	11 July 2014
Adoption by PDCO for final release	15 August 2014

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.

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](#).

Product	Needs
Anti-infectives	
Quinolone eye drops	Data on safety and efficacy <1 year of age
Corticosteroids	
Dexamethasone	Data on safety and efficacy of intravitreal formulations
Mydriatics & Cycloplegics	
Atropine sulfate	Data on safety and efficacy
Cyclopentolate HCL	Preparation with better tolerability/acceptability ("non-stinging") Data on safety and efficacy <3 months of age
Antiglaucoma	
Betaxolol	Data on safety and efficacy
Bimatoprost	PIP agreed for "Treatment of glaucoma"
Latanoprost	PIP agreed for "Treatment of glaucoma"
Timolol	Age-appropriate, preservative-free preparation
Travoprost	PIP agreed for "Treatment of glaucoma"
Diagnostics and perioperative preparations	
Acetylcholine chloride	Data on safety and efficacy
Apraclonidine	Data on safety and efficacy under 12 years of age
Diclofenac sodium	Data on safety and efficacy
Antineovascularisation agents	
Anti-VEGF mAb	Safety and efficacy in the treatment of retinopathy of prematurity (ROP)
Immunosuppressants	
Ciclosporin	PIP agreed for "Treatment of vernal keratoconjunctivitis"