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Human Medicines Development and Evaluation

Inventory of paediatric therapeutic needs

Cardiovascular therapeutic area

Agreed by PDCO	August 2012
Adopted by PDCO for release for consultation	15-17 August 2012
Start of public consultation	30 August 2012
End of consultation (deadline for comments)	30 October 2012
Agreed by PDCO	November 2012
Adoption by PDCO for final release	7 December 2012

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 therefore 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, however, 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 any 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](#).

CARDIOVASCULAR THERAPEUTIC AREA

Refer to the therapeutic areas of **nephrology** [e.g. for ACE-inhibitors, diuretics, calcium-antagonists, AT-II receptor antagonists ('sartans')] and **metabolism** [e.g. for 'statins'] as soon as they are published.

Product	Needs
Inotropes, Phosphodiesterase Inhibitors, Inodilators, Vasodilators	
Arginine-vasopressin	For treatment of cardiogenic shock: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Bosentan	PIP agreed for 'treatment of pulmonary arterial hypertension (PAH)'
Dobutamine	PIP agreed for 'treatment of neonatal circulatory failure'
Dopamine	PIP agreed for 'treatment of vascular hypotension disorder'
	For prevention and treatment of low cardiac output syndrome (LOCS): <ul style="list-style-type: none"> • Data on safety and efficacy
Epinephrine (adrenaline)	For prevention and treatment of low cardiac output syndrome (LOCS): <ul style="list-style-type: none"> • Data on dose, safety and efficacy • Age appropriate formulation for neonates.
Levosimendan	For treatment of heart failure, and prevention and treatment of low cardiac output syndrome (LOCS): <ul style="list-style-type: none"> • Data on dose, safety and efficacy
Nitric oxide (NO)	For treatment of persistent pulmonary hypertension of the newborn (PPHN): <ul style="list-style-type: none"> • Data on efficacy and safety in preterm infants below 34 weeks of gestational age (GA)
Nitroprusside	For treatment of heart failure and hypertensive crisis, and prevention and treatment of low cardiac output syndrome (LOCS): <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Norepinephrine	For treatment of acute hypotension: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy in children including preterm and term neonates • Age appropriate formulation
Prostracyclin and related analogues	For pulmonary hypertension and treatment of low cardiac output syndrome (LOCS): <ul style="list-style-type: none"> • Data on PK, safety and efficacy

Product	Needs
Sildenafil	PIP agreed for 'treatment of pulmonary arterial hypertension'
Anti-hypertensive (central action mechanism)	
Clonidine	For treatment of hypertension: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate oral formulation
α- and β-Blockers	
Labetalol	For treatment of hypertension: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
β-Blockers	
Atenolol	For treatment of hypertension and arrhythmias: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy in children below 12 years of age including neonates
Bisoprolol	For treatment of chronic heart failure: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Carvedilol	For treatment of hypertension and heart failure: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Esmolol	For treatment of hypertension and arrhythmias: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Metoprolol	For treatment of hypertension and arrhythmias: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Propranolol	For treatment of hypertension and supraventricular tachycardia: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy
Sotalol	For treatment of supraventricular and ventricular arrhythmias: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation

Product	Needs
Other Anti-arrhythmics	
Adenosine phosphate	For cardioversion and treatment of supraventricular tachycardia: <ul style="list-style-type: none"> • Data on dose, safety and efficacy • Age appropriate formulation
Amiodarone	For treatment of arrhythmias: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Flecainide	For treatment of arrhythmias: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy in children below the age of 12 years • Age appropriate formulation
Anti-thrombotics	
Acetylsalicylic acid (aspirin)	For treatment of Kawasaki disease: <ul style="list-style-type: none"> • Age appropriate formulation For prevention of thromboembolic events: <ul style="list-style-type: none"> • Data on safety and efficacy • Age appropriate formulation
Alteplase	For intravascular and catheter related thrombolysis: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Clopidogrel	PIP agreed for 'prevention of thromboembolic events'
Low molecular weight heparins	For prevention and treatment of thrombosis: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation
Urokinase	For intravascular thrombolysis: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy
Warfarin	For prevention and treatment of venous thrombosis and pulmonary embolism: <ul style="list-style-type: none"> • Data on PK/dose, safety and efficacy • Age appropriate formulation

Abbreviations:

PIP Paediatric Investigation Plan

PK pharmacokinetics