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Human Medicines Development and Evaluation

Inventory of paediatric medicines

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

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

Objective of the list

The Paediatric Committee at the European Medicines Agency (PDCO) is working to identify the needs in the different therapeutic areas where there should be research and development of medicinal products for children. Products are listed in alphabetical order within the product classes, not in any order of priority.

Disclaimer

The lists should not be viewed as a prescription tool nor as recommendations for treatment. Accuracy of data cannot be guaranteed.

Information on the authorisation status of medicinal products as well as on available formulation authorisations is limited and not available for all European Member States. Accuracy of the information provided on the authorised indication, population and formulation(s) therefore cannot be guaranteed by the European Medicines Agency (EMA). 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 PIPs on listed products, etc).

Notes

Information in the 2nd column (authorised indication) includes the indication in broad terms only. The 3rd column refers to the population for which the medicine is authorised in at least one Member State and formulation(s) authorised in at least one Member State.

For the designation of the products International Nonproprietary Names (INN) are used whenever possible.

The shaded products represent those where a decision has been adopted on a Paediatric Investigation Plan (PIP). For further information please consult the EMA website. The information in the 2nd column in this case represents the condition in the PIP decision.

CARDIOVASCULAR THERAPEUTIC AREA

Refer to **nephrology** [e.g. for ACE-inhibitors, diuretics, calcium-antagonists, AT-II receptor antagonists ('Sartans')] and **metabolism** [e.g. for 'statins']

Product	Authorised indication	Authorised population, formulation	Needs
Inotropes, Phosphodiesterase Inhibitors, Inodilators, Vasodilators			
Arginine-vasopressin	Cardiogenic shock	Adults Solution for injection	Data on PK, dose, safety and efficacy Age appropriate formulation
Bosentan			PIP agreed
Dobutamine	Cardiogenic shock, acute heart failure	Children Concentrate for solution for infusion	Data on efficacy in neonates * <i>* Please note that there is a need for international consensus on the definition of 'shock' in neonates, and any medicine development should take this into consideration</i> Age appropriate formulation
Dopamine			PIP agreed
Hydroxyethyl starch (tetrastarch)	Shock, cardiac failure	Adults Solution for infusion	Data on efficacy and safety versus normal saline solution (NaCl 0.9%)* <i>* Please note that there is a need for international consensus on the definition of 'shock' in neonates, and any medicine development should take this into consideration</i>
Levosimendan	Acute decompensation of chronic heart failure	Adults Concentrate for solution for infusion	Data on safety, efficacy and dose

Product	Authorised indication	Authorised population, formulation	Needs
Nitric oxide (NO)	Pulmonary hypertension Pulmonary hypertension in conjunction with heart surgery	≥ 34 weeks of gestational age (pulmonary hypertension) Adults and children (pulmonary hypertension in conjunction with heart surgery) Inhalation gas	Data on efficacy and safety for treatment of pulmonary hypertension in preterms infants < 34 weeks gestational age
Nitroprusside	Shock, hypertensive crisis	Adults Solution for infusion	Data on safety, efficacy and PK/dose Age appropriate formulation
Norepinephrine	Acute hypotension	Adults Concentrate for solution for infusion	Data on safety, efficacy and PK/dose in children including preterm and term neonates Age appropriate formulation
Sildenafil			PIP agreed
Hypertension Central Action Mechanism			
Clonidine	Hypertension	Adults Tablet, capsule, solution for injection	Data on PK/dose, efficacy, safety Age appropriate oral formulation
α- and β- Blockers			
Labetalol	Hypertension emergencies, hypertension	Adults Film-coated tablet, solution for injection	Data on PK/dose, efficacy, safety Age appropriate formulation
β- Blockers			
Atenolol	Hypertension, arrhythmias	Adults and children > 12 years Tablet, film-coated tablet, solution for injection or infusion, syrup	Data on PK/dose, efficacy, safety in children < 12 years including neonates

Product	Authorised indication	Authorised population, formulation	Needs
Bisoprolol	Chronic heart failure	Adults Tablet, film-coated tablet	Data on PK/dose, efficacy, safety Age appropriate formulation
Carvedilol	Hypertension, heart failure, angina	Adults Tablet	For treatment of hypertension and heart failure: Data on PK/dose, efficacy, safety Age appropriate formulation
Esmolol	Hypertension, arrhythmias	Adults Solution for injection, concentrate for solution for infusion	Data on PK/dose, efficacy, safety Age appropriate formulation
Metoprolol	Hypertension, arrhythmias	Adults Tablet, solution for injection	Data on PK/dose, efficacy, safety Age appropriate formulation
Propranolol	Hypertension, arrhythmias, Tetralogy of Fallot	Adults and children Tablet, solution for intravenous infusion, oral solution	For treatment of hypertension and supraventricular tachycardia: Data on PK/dose, efficacy and safety
Sotalol	Supraventricular and ventricular arrhythmias	Adults Tablet	Data on PK/dose, efficacy, safety Age appropriate formulation

Product	Authorised indication	Authorised population, formulation	Needs
Other Anti-Arrhythmics			
Adenosine phosphate	Supraventricular tachycardia – Cardioversion	Adults Solution for injection	Data on dose, efficacy, safety Age appropriate formulation
Amiodarone	Arrhythmias	Adults Tablet, solution for injection	Data on PK/dose, efficacy, safety Age appropriate oral formulation
Flecainide	Arrhythmias	Adults and children > 12 years Tablet, capsule, solution for injection	Data on PK/dose, efficacy, safety in children < 12 years Age appropriate formulation
Antithrombotics			
Acetylsalicylic acid (aspirin)	Prevention of thrombotic cerebrovascular or cardiovascular disease and following by-pass surgery Kawasaki disease	Adults and children Tablet, chewable tablet, gastro-resistant tablet, effervescent tablet, granules	For Kawasaki disease: Age appropriate formulation
Alteplase	Thrombolytic treatment in myocardial infarction and pulmonary embolism Fibrinolytic treatment of acute ischaemic stroke	Adults Powder and solvent for solution for injection and infusion	For intravascular and catheter related thrombolysis: Data on PK/dose, efficacy, safety Age appropriate formulation

Product	Authorised indication	Authorised population, formulation	Needs
Clopidogrel			PIP agreed
Low molecular weight heparins	Prevention and treatment of thrombosis	Adults Solution for injection	Data on PK/dose, efficacy, safety Age appropriate formulation
Urokinase	Intravascular thrombolysis, thrombosed haemodialysis shunts and catheters	Adults Children (thrombosed central venous catheters) Powder for solution for injection or infusion	For intravascular thrombolysis in children: Data on PK/dose, efficacy, safety
Warfarin	Prevention and treatment of venous thrombosis and pulmonary embolism	Adults Tablet, oral suspension	Data on PK/dose, efficacy, safety Age appropriate formulation