



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 August 2015  
EMA/471041/2015

## Overview of comments received on the list of paediatric needs – Endocrinology

### Comments from:

Name of organisation or individual
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(1) Helmut Küster, MD, Chief, Neonatology, University Children's Hospital Göttingen, Germany
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## 1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
n/a	n/a	n/a

## 2. Specific comments on text

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
Categories			
Insulins	(1)	<p>Comment: Human insulin for low glucose tolerance in the first week of life.</p> <p>Proposed change: Data on PK, PD, efficacy and safety in newborns, especially extremely immature preterm infants with a gestational age &lt;26 weeks. Data on long-term safety.</p>	Products to address medical needs specific to pre-term and term neonates will be included in a separate "Inventory of paediatric needs Neonatology" which is currently under preparation.
Suggest addition to "Corticosteroids" section (Page 2 of document)	(1)	<p>Comment: Hydrocortisone for a) for low blood pressure in the first week of life b) for treatment of Bronchopulmonary Dysplasia</p> <p>Proposed change: Data on PK, PD, efficacy and safety in newborns, especially extremely immature preterm infants with a gestational age &lt;26 weeks. Data on long-term safety.</p>	Products to address medical needs specific to pre-term and term neonates will be included in a separate "Inventory of paediatric needs Neonatology" which is currently under preparation.