Paediatric Adverse Events in MedDRA

1. Uses of the Paediatric Adverse Events List

One of the key drivers for development of the Paediatric Adverse Event Terms List is to support pharmacovigilance activities in surveillance of adverse events in the pediatric population. Medicinal products may affect physical and cognitive growth and development, and adverse event profiles may differ in pediatric patients. Because developing systems may respond differently than mature adult organs, some adverse events and drug interactions that occur in pediatric patients may not be identified in adult studies and therefore need specific monitoring. In addition, dynamic processes of growth and development may not manifest adverse events acutely, but at a later stage of growth and maturation.

For aggregate data analysis of adverse drug events observed in the paediatric population, it is recommended that the relevant age groups provided in the Individual Case Safety Reports (ICSRs) be taken into account. When no age information is available, the Paediatric Adverse Event Terms List can facilitate overall monitoring of adverse events in this population.

The Paediatric Adverse Event Terms List is intended as recommendation only, providing a basis for a common understanding of pediatric adverse event terms and leaving organizations the option to modify the list – either adding terms or deleting terms – according to their own organization specific needs.

2. Development of the Paediatric Adverse Event Terms List

The preparation of the Paediatric Adverse Event Terms List consisted of identifying the MedDRA Preferred Terms (PTs) that are specific to the paediatric population. Initially, all PT terms in MedDRA with the following roots/words were identified:

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<thead>
<tr>
<th>Paediatric Roots/Words</th>
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<td>Accel</td>
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<td>Newborn</td>
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The retrieved PT terms were then reviewed by an MSSO physician and the list completed by drilling up and down into the MedDRA hierarchy. The list was additionally reviewed by external pharmacovigilance experts (the EudraVigilance Expert Working Group and the EMEA Paediatric Committee).

The inclusion criteria are:
• Terms that relate exclusively to the paediatric population.  
  e.g., PT Neurotic disorder of childhood

• Terms for conditions that could occur in the non-paediatric population but are 
  characteristic or more common in the paediatric age group.  
  e.g., PT Varicella

• Terms for maternal disorder(s) that directly impact the fetus or newborn.  
  e.g., PT Maternal hypertension affecting foetus

The exclusion criteria are:

• Terms for conditions that occur exclusively (or nearly exclusively) in the adult 
  population e.g., PT Parkinson's disease

• Pregnancy-related terms (including placental and amniotic conditions) that do 
  not necessarily result in a harm to the fetus or newborn e.g., PT Retained 
  placenta or membranes

• Paediatric terms that are not typically adverse events/adverse drug reactions.  
  Such terms are found primarily in SOC Social circumstances, e.g., PT 
  Childhood