Prequalification and Paediatric Medicines

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Red Crescent Museum
Geneva

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Prequalification and paediatric medicines

- The WHA Resolution 60.20 – **Better Medicines for Children**
- The WHA Resolution 69.20 – **Promoting Innovation and access to quality, safe, efficacious and affordable medicines for children**
- To take all necessary measures to support **access to quality, safe, effective and affordable medicines for children**
- To strengthen research and development on appropriate medicines for diseases that affect children and ensure that **high-quality clinical trials** are undertaken
- To strengthen **national regulatory systems including pharmacovigilance and post-market surveillance**
Prequalification steps to facilitate access to novel quality assured paediatric formulations

• Waiver of clinical safety/efficacy or bioequivalence data requirements
  o No new clinical efficacy/safety data needed for first time FDCs of existing molecules if bioequivalent to a combination of the monocomponent products (ref WHO FDC guideline, 2004)
  o Application of BCS biowaivers principles for products containing BCS class 1 or 3 products even if a pharmaceutical equivalent comparator product does not exist
  o Ongoing work to identify APIs eligible for BCS based biowaiver

• Working with stakeholders and joint initiatives (pharma + DNDi/MMV) to facilitate prequalification and development of unique pediatric products
  o e.g. artesunate rectal capsules (MA124 from Cipla now prequalified, others close to prequalification), 4FDC “sprinkles” formulation under discussion

PQ and Paediatric medicines: 23 May 2018, Geneva
Other assistance to enable access to paediatric medicines

- Product specific guidance documents to manufacturers, e.g.,
  - Product specific BE design and comparator advice
  - Adapting BE study designs to account for pediatric strength to adult strength differences
- Pre-submission meetings with Prequalification to facilitate and provide guidance
- Increased visibility of invited paediatric formulations in Prequalification EOIs (subsections dedicated to paediatrics)
- Use of the Collaborative Registration Procedure (CRP) to facilitate national registration of prequalified products
- Use of the Expert Review Panel (ERP) mechanism to enable procurement of products not yet prequalified
  - e.g., TB products of new paediatric strengths and sulfadoxine/pyrimethamine based pediatric formulations
### Prequalified paediatric products as of 18 May 2018*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Paediatric Formulations</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>41</td>
<td>21% of all listed products</td>
</tr>
<tr>
<td>Malaria</td>
<td>11</td>
<td>23% of all listed products</td>
</tr>
<tr>
<td>TB</td>
<td>14</td>
<td>14% of all listed products</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>3</td>
<td>100% of all listed products</td>
</tr>
</tbody>
</table>

* Includes oral liquids, granules, rectal capsules, injectable, dispersible tablets, tablets, etc. of specific paediatric strengths

* Does not include adult products suitable for paediatric use, such as scored tablets
Regulatory challenges and ongoing initiatives

- Harmonizing safety/efficacy regulatory requirements for paediatric products, including tools to identify appropriate paediatric strengths.
  - Collaboration with WHO clinical departments, fellow regulators and ICH working groups

- List of excipients acceptable for use in paediatrics

- Ensuring acceptability/palatability for paediatric consumption

- Continuing development of product-specific guidance as necessary

- Reactivation of the Paediatric Medicines Regulators Network
GAP-f: Collaboration across sectors to ensure accelerated development and uptake

A collaborating platform supported by an innovative financing mechanism that promotes a faster, more efficient and more focused approach to pediatric clinical and formulation development and introduction.