WHO Medicines Prequalification: What is it and why is it important?

Reproductive Health Supplies Coalition, 16th Meeting
Oslo, 7 October 2015

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Mission of WHO medicines prequalification: ensure timely availability of quality-assured health products for priority diseases and reproductive health in low- and middle-income countries

<table>
<thead>
<tr>
<th>Goal</th>
<th>Key outputs</th>
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<tr>
<td>Make quality priority products available in a consistent and timely manner</td>
<td>Lists of prequalified products and QCLs</td>
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<td>Ensure sustainable supply of quality-assured products</td>
<td>WHO public assessment/inspection reports</td>
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<td>Create national capacity to evaluate and monitor ongoing quality of products</td>
<td>Accelerated national registration of prequalified products</td>
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**Strategy**
- Apply and promote unified quality, safety and efficacy/performance standards, for comprehensive evaluation of health products
- Build capacity of staff of regulatory authorities, quality control laboratories and manufacturers

**Key outputs**
- Increased regulatory capacity at national level
- Improved good manufacturing practice
Medicines prequalification: assessment of quality, safety, efficacy / performance, with focus on specific needs of resource-limited settings

- **As well as strengthening** manufacturers’ and national regulatory **capacity**
- **Programmatic suitability**: specific emphasis on issues of particular relevance to resource-limited settings, such as:
  - Stability of products (heat conditions)
  - Adapted: appropriate formulation
- **Life cycle management** of products
WHO medicines prequalification: benefits for stakeholders (1)

**Patients**

- Access to quality-assured products, adapted to their specific needs
- Appropriate and effective treatment

**WHO Member States & NRAs**

- Reduced burden of regulatory approval
- Increased regulatory capacity & harmonization of regulatory practices in countries
- Implementation of specifically developed and road-tested international guidelines
- Access to quality-assured products

**Donors, procurers and UN agencies**

- List of prequalified products and laboratories
- Increased availability of quality-assured products
- Monitoring quality of prequalified products
- Diversity and affordability of products → healthier markets
### WHO medicines prequalification: benefits for stakeholders (2)

#### Manufacturers

- Access to donor-sponsored tenders
- Faster regulatory approval
- Timely assessment of variations and changes
- International quality-assured product status (improved image)
- Recognition of GMP status, beyond prequalified products
- Increased capacity in quality management systems
- Target product profiles
- Harmonization of regulatory practices within WHO Member States
- Reduced operating and manufacturing costs

#### QC labs

- International recognition of prequalified QCLs
- Technical assistance and scientific advice
Medicines PQ = a global public good

"The prequalification programme could continue for a long time, with a slowly changing range of essential medicines of great public interest, each in its own market development cycle...The WHO PQP has become a global public good that has helped save millions of lives...It is the strongest mechanism currently in place to create sustainable regulatory systems in low- and middle-income countries. This alone justifies investment in WHO PQP."
...but not all by itself

WHO disease & treatment prog. 

UN agencies 

WHO PQ 

WHO CC 

QC labs 

CROs 

Manufacturers 

Donors 

NRAs 

Procurers 

Member States 

Health care providers 

Patients 

CRO = contract research organization 
QC lab = quality control laboratory 
WHO CC = WHO collaborating centre
However...less prequalification success with reproductive health medicines

- Too much focus on price
- For manufacturers: not enough evidence that quality pays
- Regulatory expense
- Technically difficult (oxytocin, DMPA, misoprostol)
- Low demand (magnesium sulphate)
- Too few quality-assured products

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<tbody>
<tr>
<td>Accepted for Assessment</td>
<td>10</td>
<td>4</td>
<td>7</td>
<td>7</td>
<td>3</td>
<td>3</td>
<td>14</td>
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<td>6</td>
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<tr>
<td>Cum. total</td>
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<td>14</td>
<td>21</td>
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<td>34</td>
<td>48</td>
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In total 73 applications were submitted to PQP

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In total 28 products were prequalified by WHO-PQT + 1 listed based on EMA Art 58 approval

Applications accepted 2007–2015, at 9 Sept 2015
What would make a difference?

Procurers:
- Forecasting information
- Harmonized standards for international/national procurement of quality-assured products

Regulators & manufacturers:
- More sharing of assessment and inspection reports/use of collaborative procedure for accelerated registration

WHO prequalification:
- Continued and sustained outreach to manufacturers pre-application
- Improved accessibility of information about prequalification.

Thank you for your attention