WHO Pre-Qualification Programme: Facilitating Regional Approval and Patient Access to Treatments

A Decade of R&D for Neglected Diseases in Africa
Nairobi, Kenya, 4-5 June 2013

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Tanzania Food and Drugs Authority
Tanzania Food and Drugs Authority (TFDA)

- **Executive Agency** under the Ministry of Health and Social Welfare
  - established in 2003 under the Tanzania Food, Drugs and Cosmetics Act, Cap 219.

- **Regulatory body** mandated to regulate safety, quality and effectiveness of food, medicines, cosmetics and medical devices.

- TFDA has put in place key regulatory systems, processes and procedures *(Certified to ISO 9001:2008).*
  - Marketing authorization/registration + GMP Inspection
  - Market control (post-marketing surveillance)
  - Pharmacovigilance & Clinical trials control

Prequalification of Medicines Programme

Since 2001 the UN Prequalification Programme managed by WHO is ensuring that medicines procured with international funds are of assessed and inspected for quality, efficacy and safety, involves

- Prequalification programme for medicines (finished dosage forms)
- Prequalification of active pharmaceutical ingredients (APIs)
- Prequalification of quality control (QC) laboratories

The Prequalification Programme is an action plan for expanding access to priority essential medicines in the following four areas:

- HIV/AIDS
- Tuberculosis
- Malaria
- Reproductive Health

- Selected individual products for other diseases (Flu, Zinc sulphate)
Medicines Prequalification Process

- **Expression of Interest**
- **Product dossier SMF**
- **Assessment**
  - Additional information and data
- **Inspections**
  - Corrective actions
- **Compliance**
  - Handling of complaints
  - Compliance maintenance (variations)
- **Prequalification**
- **Monitoring**
Capacity building provided a core value of the programme

Participants in various capacity building workshops organized or co-organized by PQP during 2007–2012
WHO – EAC Joint Pilot Project

- Launched in March 2010 involving two products
  - **Abacavir** (as sulphate) 60mg tablets for oral suspension & **Amikacin** 500mg/2ml injection solution
  - Applications simultaneously submitted to WHO PQ and EAC NMRAs
  - Assessments conducted in Copenhagen - WHO PQ Programme expertise to provide direct support to EAC assessors (2 from each NMRA)

- Products prequalified and registered in countries simultaneously – **accelerated access**

- Platform for **mutual recognition** of regulatory decisions in future (medicines harmonization process in EAC)
## Outcome of the project

### Joint WHO-EAC Assessment

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Date submitted to WHO</th>
<th>Review start date</th>
<th>Review completion date</th>
<th>Date prequalified</th>
<th>Review time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir (as sulfate) 60mg tablets</td>
<td>15th January 2010</td>
<td>12th March 2010</td>
<td>17th July 2010</td>
<td>26th August 2010</td>
<td>Four (4) Months</td>
</tr>
<tr>
<td>Amikacin sulfate 500mg/2ml injection</td>
<td>3rd December 2009</td>
<td>12th March 2010</td>
<td>20th November 2010</td>
<td>14th January 2011</td>
<td>Eight (8) months</td>
</tr>
</tbody>
</table>
### Outcome of the project ....

**Abacavir (as sulfate) 60mg tablets**

<table>
<thead>
<tr>
<th>Country</th>
<th>Date received</th>
<th>Date registered</th>
<th>Time taken to register</th>
<th>Time taken after joint review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenya</td>
<td>31st March 2011</td>
<td></td>
<td>Seven (7) months</td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td>22nd June 2010</td>
<td>4th October 2010</td>
<td>Three (4) months</td>
<td>Three (3) months</td>
</tr>
<tr>
<td>Uganda</td>
<td>26th May 2010</td>
<td>14th October 2010</td>
<td>Five (5) months</td>
<td>Three (3) months</td>
</tr>
</tbody>
</table>

**Amikacin sulfate 500mg/2ml injection**

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<td>-</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tanzania</td>
<td>3rd May 2011</td>
<td>9th June 2011</td>
<td>One (1) Month</td>
<td>Seven (7) months</td>
</tr>
<tr>
<td>Uganda</td>
<td>26th November 2010</td>
<td>7th June 2011</td>
<td>Seven (7) months</td>
<td>Seven (7) months</td>
</tr>
</tbody>
</table>
WHO Collaborative Procedure to accelerate registration of prequalified medicines – 90 days

- Procedure drafted in wide consultation, approved by WHO advisory expert committee.
- Pilot testing ongoing with 10 interested countries

<table>
<thead>
<tr>
<th>Botswana</th>
<th>Nigeria</th>
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<td>Tanzania</td>
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<tr>
<td>Ghana</td>
<td>Uganda</td>
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<tr>
<td>Kenya</td>
<td>Zambia</td>
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<tr>
<td>Namibia</td>
<td>Zimbabwe</td>
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</tbody>
</table>

Principles of the process

1. Procedure voluntary for manufacturers and NMRAs and providing benefits to both parties

2. Being asked by PQP holders (manufacturer), PQP shares full PQP assessment and inspection outcomes with interested NMRAs and provides advice to facilitate national regulatory decisions (registrations, variations, withdrawals).

3. No interference with national legislation, decision process and regulatory fees – availability of PQP expertise.
Principles of the process

4. Cooperation among PQP holder (manufacturer), NMRA in interested country and PQP necessary to overcome confidentiality issues, assure information flow and product identity, registration dossier in countries in principle the same as approved by PQP.

5. Each participating authority commit to adopt registration decision within 90 days from having available full PQP assessment and inspection outcomes and has the right to
   – decline to adopt procedure for individual medicines
   – Decide differently from PQP, but keep PQP informed and clarify the reasons for deviation
What PQ has offered to the regulators and industries in the regions?

• **Regulators**
  – Capacity building/training – improved technical knowledge and skills
  – Practice and experience for collaboration and cooperation
  – Offers a lot of practical tools and guidelines
  – Helps to build more credible regulatory systems
  – Save resources

• **Industries**
  – Access to international funds
  – Better quality production/products/regulatory knowledge – better access to markets
  – Better image, more trust from procurement and regulators
Conclusions

• PQP is a powerful and effective mechanism to promote access to quality medicines
  ✔ is a major proactive contributor to capacity building both for regulators and local manufacturers
  ✔ promotes collaboration and cooperation among regulators, including relying on each others work and reducing duplications

  • Played a significant role to the progress recorded in EAC Medicines Regulation Harmonization Project – a showcase for medicines regulatory harmonization in Africa

  ✔ is not a replacement for national regulatory systems but a (time limited) mechanism to promote access to quality medicines