2008 - 2018: looking back and looking forward for building universal access to quality-assured medicines

Because HEALTH Seminar

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Quality Assurance Team

Mission

Enable procurement of the health products complying to internationally-recognized norms and standards, assure continuity of supply, and facilitate access to innovative products through policies, communications with countries, data sharing and compliance verification exercise.

<table>
<thead>
<tr>
<th>Value driver</th>
<th>Description of value</th>
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<tbody>
<tr>
<td>Safety</td>
<td>• Ensure products procured with GF funds are safe, efficacious and of assured quality</td>
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<tr>
<td>Access</td>
<td>• Support introduction to innovative products through Expert Review Panel (ERP) process</td>
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<tr>
<td>Availability</td>
<td>• Work to ensure continuity of supply</td>
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<tr>
<td>Compliance</td>
<td>• Guarantee that products procured with GF funds adhere to GF internal policies and guidelines</td>
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In full alignment with TGF 2022-2017 Strategy: Maximize impact against HIV, TB and Malaria
Quality Assurance requirements

Developed under a framework of Policies and Guide making reference to WHO internationally recognized guidance and few educational guidelines for Recipients – Policy and guide are mandatory as part of GF regulation.

- **QA Policy Pharmaceutical Products** (since December 2010)
- **Quality Assurance Policy for Diagnostic Products** (Revised in May 2017)
- **Condoms**
  - **WHO Procurement Guidelines**
- **Global Fund Quality Assurance for Health Products**
- **Long Lasting Insecticidal Nets, IRS**
  - **WHOPES recommendations, WHO PQ, WHO Public Health Pesticides Procurement guidelines**
QA Policy for Pharmaceutical Products

Three pillars of quality assurance policy

1. Clinical Criteria
   ✓ Medicines listed in WHO EML or national or institutional Standard Treatment Guidelines
   ✓ Require applicants/recipients to provide justification for selection of unlisted products in one of the STGs

2. Quality Criteria
   ✓ For all products:
     ➤ Authorization for use in the recipient countries
   ✓ For ARVs, anti-TB and anti-malarial products
     ➤ Specific requirements

3. Monitoring Quality
   ✓ Monitoring quality of products all along the supply chain

4. Implementing Pharmacovigilance
   ✓ Monitoring ADRs of pharmaceutical products
## Marketing Authorization of core FPPs: ARVs, TBs & Malaria Products

### Reliance on stringent mechanism in addition to national mechanism

<table>
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<tr>
<th>MA MECHANISM</th>
<th>DESCRIPTION</th>
<th>AUDIT PRACTICES</th>
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<tbody>
<tr>
<td>Stringent Drug Regulatory Authorities (SRA)</td>
<td>• Robust legal/regulatory environment&lt;br&gt;• ICH Requirements&lt;br&gt;• Experienced &amp; Skilled Staff in Q/S/E</td>
<td>• Regular GMP inspection as per related regulation&lt;br&gt;• Mutual Recognition Agreement&lt;br&gt;• Prioritization based on risks</td>
</tr>
<tr>
<td>WHO PQ program</td>
<td>• Programme managed by WHO which prequalifies medicines considered by GF to be acceptable for procurement&lt;br&gt;• WHO requirements&lt;br&gt;• Experienced &amp; Skilled Staff in Q/S/E</td>
<td>• Regular GMP inspection as per WHO PQ Procedure&lt;br&gt;• Consideration of SRA decision&lt;br&gt;• Prioritization based on risks</td>
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<tr>
<td>Expert Review Panel (ERP)</td>
<td>• Alternative mechanism used upon GF request&lt;br&gt;• Panel of external technical experts reviewing the potential risks/benefits to use an FPP that is not yet WHO-prequalified or SRA-authorized&lt;br&gt;• Typically used for innovative products&lt;br&gt;• Supported by WHO</td>
<td>• Proof of GMP Compliance but no Routine Inspection&lt;br&gt;• Consideration of SRA &amp; WHO PQ &amp; PICS related countries Inspections</td>
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Risk for the quality of pharmaceutical products

Continuously review current risk assessment related to quality of health products and adequacy of risk mitigations.
# Primary role of the National Regulatory Authority

## Product Life Cycle

<table>
<thead>
<tr>
<th>Stage</th>
<th>Primary actor</th>
<th>Nat. Controls</th>
<th>GlobalFund</th>
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</thead>
<tbody>
<tr>
<td>Design &amp; Development</td>
<td>Product, services &amp; API Manufacturer</td>
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<tr>
<td>Manufacturing</td>
<td>NRA</td>
<td>CRO</td>
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<tr>
<td>Registration / Market Authorization</td>
<td>National program</td>
<td>NRA (GMP, GCP)</td>
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<tr>
<td>Selection</td>
<td>NPA</td>
<td>MoH</td>
<td></td>
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<tr>
<td>Procurement</td>
<td>In-country Supply Chain actors*</td>
<td>NPA</td>
<td></td>
</tr>
<tr>
<td>Import, Storage &amp; Distribution</td>
<td>Practitioners, Pharmacists, Patients</td>
<td>NRA</td>
<td></td>
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<tr>
<td>Dispensation &amp; Use</td>
<td>Manufacture</td>
<td>NRA</td>
<td></td>
</tr>
<tr>
<td>Pharmacovigilance (PV)</td>
<td>NRA</td>
<td>NRA</td>
<td></td>
</tr>
<tr>
<td>Market surveillance</td>
<td>Manufacturer</td>
<td></td>
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<tr>
<td>Maintenance &amp; End of life</td>
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**Notes:**
- PV: Pharmaco-vigilance
- QC: Quality Control
- GF PR (based on QA policy & guidance)**: Global Fund Product Registration
Building Resilient Regulatory System

Challenges

- Multiple structure/institutions in place, overlapping responsibilities
- Not adequate structure in place, no distribution of authority, unclear line of authority & reporting
- No processes in place, lack of documentation
- Not adequate number of staff to perform technical and administrative tasks
- Lack of competencies to execute regulatory & scientific tasks
- Lack of adequate tools, IT System, Reference documentation

Supporting Regulators to satisfy their hierarchy of needs
Communication Challenges in the QA Ecosystem

Quality assurance ecosystem

Robust Regulatory Authorities

Pre-qualification, Market Authorizations, variations

Manufacturers

International financing channels

Post market assurance

National authorities

Quality related interaction

Challenges

1. Limited capacity of countries to generate adequate information in a timely manner

2. Insufficient quality information from the field reach the SRA to effectively act up

3. Manufacturers informing predominantly RRA and only partially countries on quality & safety issues

4. Very limited quality information from the field reach the manufacturer

5. Limited sharing of information between countries and partners

Source: GF

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Thanks for your attention