Procurement policies and requirements

JOINT UNICEF, UNFPA & WHO meeting

with manufacturers,

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Organizations who contributed to this presentation

- **WHO** Prequalification of Medicines Programme (PQP)
- **WHO** Global Procurement and Logistics unit (GPL)
- **UNICEF** Supply Division Copenhagen, Denmark
- **MSF** - Médecins Sans Frontières
- **Global Fund** to Fight AIDS, Tuberculosis and Malaria
- **ICRC** - International Committee of the Red Cross
- **UNFPA** - United Nations Population Fund
Outline of presentation

1. QA policies for medicines, diagnostics and other products
2. Procurement and pre-shipment testing
3. Monitoring product quality
1. QA policies
## Stringent standards for key pharmaceuticals

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>ARVs, anti-TB, anti-malarials</th>
<th>Reproductive health</th>
<th>Other essential medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO-pre-qualified (PQ)</strong> (UNICEF, WHO, MSF, ICRC)</td>
<td>As per Global Fund QA policy, applied similarly by most other agencies</td>
<td>WHO-PQ $^1$, or Approved by a Stringent Regulatory Authority (SRA) ICH members, observers and associates $^3$</td>
<td>Authorized for use in destination country; Agencies’ own qualification GMP audit &amp; dossier assessment (UNICEF, MSF, ICRC, UNFPA) Recognition of WHO-PQ (selected meds) and SRA approval</td>
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<tr>
<td><strong>or SRA-approved (UNICEF, MSF, ICRC)</strong></td>
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<tr>
<td>If products meeting these criteria are not available on the market:</td>
<td>Rapid risk review by ERP or Agencies’ own qualification</td>
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</table>
Rapid risk review by Expert Review Panel (ERP)\(^4\)

**Dossier assessment**
Product dossier must have been accepted for review by WHO-PQP or an SRA (if the medicine/strength is invited for WHO prequalification)

\(\blacktriangledown\) ERP reviews abridged dossier

**Inspection**
Manufacturing site (production line) must be GMP-certified by WHO-PQP or by an ICH or PIC/s member

\(\blacktriangledown\) ERP verifies GMP status

Positive ERP opinion is valid for one year
Outcomes\(^5,6\) are used by:
Global Fund; GDF; UNITAID, UNFPA; MSF; ICRC; UNICEF (for ACTs)
Agencies’ product/supplier qualification

Harmonized principles, stringent standards
Inter-agency discussion, sharing of audit outcomes

Dossier assessment
- Common product questionnaire, based on WHO guidance\(^7\)
- Periodic requalification, risk-based every 3 to 5 years
  UNICEF and UNFPA approval is linked to bidding
MSF: monitoring of dossiers

Audit (production-line specific):
- Stringent standards: WHO-PQP, SRA, PIC/s
  (UNICEF=PIC/S Partner\(^8\))
- Recognition of other stringent audits (as per agencies’ policies)
- Periodic re-audit (risk-based, every 1-5 years)
Therapeutic equivalence

- New product questionnaire released (revised MQAS 2014)
- For generic products, demonstration of therapeutic equivalence required
- In vivo comparative bioavailability studies: comparison of performance of FPPs based rate and extent of absorption of API from each formulation
  - Area under the concentration-time curve (AUC)
  - Maximal concentration (Cmax)
  - Time to maximal concentration (Tmax)
- Comparative in vitro dissolution profile:
  - Biopharmaceutics Classification System (BCS)-based biowaivers
  - Conditions described in WHO BCS classification document (WHO Technical Report Series, No. 937, or later)
Guidance

Products that require studies to determine equivalence...

- Solid oral FPPs
  - immediate- and modified-release FPPs

- Complex topical formulations
  - emulsions, suspension, ointments, pastes, foams, gels, sprays, and medical adhesive systems

- Complex parenteral formulations
  - depot injections, nasal/inhalational suspension etc
# Diagnostic products

In vitro diagnostic products must be manufactured at a site compliant with **ISO 13485** where applicable, else ISO 9000 series

| + HIV RDTs, ELISA and W/Blot must pass | • **GHTF** founder member review (regulatory authorities of USA, Japan, EU, Canada, Australia) except for CD4 **or**
| CD4, VL, EID | • **WHO** technical assessment
| | • **ERPD**
| + Malaria RDTs must pass | • **WHO** technical assessment, **or**
| | • **Have a positive WHO advice** based on assessment to the requirements of a **GHTF** founder member

**Other RDTs** - hepatitis, dengue, leishmania, measles, rubella, syphilis, cholera

• **WHO** technical review.

Joint annual tender conducted with UNICEF
### Quality standards: Other non-pharma products

<table>
<thead>
<tr>
<th>Laboratory supplies</th>
<th>Condoms, IUDs</th>
<th>Bednets</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagents, laboratory items for general use: WHO GLI (^{11}) WHO EHT (^{12})</td>
<td>UNFPA (^{13}) Specimen, Prequalification Guidelines for Procurement And ISO 4074</td>
<td>WHOPES (^{14}) WHO Pesticide Evaluation Scheme</td>
<td>“..Products must be selected from lists of prequalified products, if any, and comply with quality standards applicable in country of use, if any.” (Global Fund)</td>
</tr>
</tbody>
</table>
2. Procurement
Common procurement principles

- Adherence to principles of WHO guidance:
  “A Model Quality Assurance System for Procurement Agencies” (MQAS)*
  Including WHO Good Practices: GMP, GDP, GSP…

- Transparent and competitive procurement processes

- Quality-assured products procured at best value for money

- Adherence to National and International Laws
Good distribution practices (GDP)

Some examples from agencies’ policy and practice:

- Technical audits/visits to procurement agencies before awarding contracts (GDF)
- Pre-shipment inspection: visual inspection at warehouse and review of CoA – shelf life, manufacturing site (GDF)
- (Planned:) Require documentation of controlled shipment conditions, including temperature control (UNICEF, MSF, ICRC, UNFPA)
### Pre-shipment Quality Control: Medicines

As per Global Fund QA policy – applied similarly by most other agencies

| Frequency             | Random, according to pre-defined testing plan  
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<td>Risk-based frequency</td>
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<td>- E.g. all of first 5-10 batches, then 10-20% as long as no quality problems</td>
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<td></td>
<td>- Less or no testing of WHO-PQ’d and SRA-approved products, except for AMFm (antimalarials)</td>
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<td></td>
<td>- Mandatory for all orders of ERP-approved products</td>
</tr>
<tr>
<td>Responsibility</td>
<td>WHO prequalified or ISO 17025-certified laboratory</td>
</tr>
<tr>
<td>Methods</td>
<td>WHO International Pharmacopoeia (Ph. Int.), US Pharmacopoeia (USP) or British Pharmacopoeia (BP) when possible</td>
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</table>
## Pre-shipment Quality Control: Non-pharma

As per Global Fund requirements – applied similarly by other agencies

<table>
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<th>Diagnostics (lot testing)</th>
<th>Condoms</th>
<th>Bednets</th>
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<tbody>
<tr>
<td>Random testing for HIV and Malaria RDTs, <strong>subject to testing capacity of WHO-recommended lab</strong></td>
<td><strong>All</strong> batches tested</td>
<td>Systematic review of Manufacturer’s CoA and random testing</td>
</tr>
<tr>
<td>Testing laboratory as per WHO guidance</td>
<td>Independent sampling agent (ISO 2859-1) Independent Laboratory ISO 17025-certified lab</td>
<td>Independent sampling agent Independent ISO-17025 certified lab WHO Collaborating Centre for QC of Pesticides</td>
</tr>
<tr>
<td><strong>Discussions among partners to better share resources</strong></td>
<td>WHO Methods and Specifications (WHOPES)</td>
<td></td>
</tr>
<tr>
<td>Methods subject to WHO guidance for product type</td>
<td>ISO 4074: 2002 standards and WHO/UNFPA Specification guideline</td>
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3. Quality monitoring
Quality monitoring during and after purchase

• Supplier commits to product identity at each delivery:
  – Confirmation in tender documents that product delivered is identical with approved product
  – Signed Product Specification Sheet (MSF) or other specific documentation accompanies each delivery

• Review of manufacturer’s CoA: Mfg. site, shelf life, trends.. (GDF)

• Compliance with specifications are checked during audits at manufacturing sites (e.g. UNICEF, MSF, ICRC, UNFPA)

• Global Fund Price and Quality Reporting system (PQR), corrective measures if non-compliant product selection

• Monitoring of complaints, quality problems, batch recalls…(GDF)
Post-shipment quality control testing

Aim: To detect additional failures due to storage, transport..

Examples of QC testing programmes:

• WHO-PQP performs QC testing surveys in countries\textsuperscript{16}

• Global Fund: Risk-based QC testing all along the supply chain by a WHO-prequalified or ISO 17025-certified laboratory
Conclusion

Agencies are aligned on the same QA principles

• Reliance on WHO-prequalification and stringent regulatory bodies (second choice: ERP)
• Use of best practices for all procurement, as defined in WHO Model QA System
• Agencies’ own internal qualification for non-ARV, anti-TB and anti-malaria medicines based on the MQAS principles

Implementation may differ slightly according to “in-house” technical resources.

Global QA can not be done in isolation.
Agencies cooperate and share information to maximize access to quality-assured products for their beneficiaries
Harmonized QA policies

- **UNICEF**: [http://www.unicef.org/supply/index_41948.html](http://www.unicef.org/supply/index_41948.html)
  Contact: pjakobsen@unicef.org, hnielsen@unicef.org

- **UNFPA**: [http://www.unfpa.org/public/home/procurement/pid/10863](http://www.unfpa.org/public/home/procurement/pid/10863)
  UNFPA’s quality assurance for RH Medicines

- **MSF**: [http://www.msf.org/msf-drugs-procurement](http://www.msf.org/msf-drugs-procurement)
  Contact: Elodie.JAMBERT@geneva.msf.org

- **Global Fund**
  Contact: joelle.daviaud@theglobalfund.org

- **ICRC** [www.icrc.org](http://www.icrc.org) ; Contact: sarsacjanvier@icrc.org
added this part
Seloi.mogatie, 18/09/2014
1. WHO Prequalification of Medicines Programme (PQP): [www.who.int/prequal](http://www.who.int/prequal)
3. SRAs: Listed in each organization’s QA policy
5. GF ERP-approved products are listed online [www.theglobalfund.org/en/procurement/quality/pharmaceutical/#Lists](http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/#Lists)
References (2)

8. PIC-S Quality System requirements for GMP inspectorates:  
   www.picscheme.org/.../PI002-3RecommendationonQualitySystem.pdf

9. Global Fund Diagnostics policy:  
   www.theglobalfund.org/en/procurement/quality/diagnostics

10. WHO PQ of diagnostics:  
    http://www.who.int/diagnostics_laboratory/evaluations/en/

11. WHO GLI  
    www.stoptb.org/wg/gli/default.asp

12. WHO EHT  
    www.who.int/medical_devices/en/index.html

13. UNFPA’s quality assurance  
    www.unfpa.org/public/home/procurement/pid/10863

14. WHOPES  
    www.who.int/whopes/resources/en

15. Global Fund publishes all pre-shipment QC testing results online  
    www.theglobalfund.org/documents/psm/CoAs/PSM_CoAs_List_en

16. WHO QC survey  
   http://apps.who.int/prequal/info_applicants/qclabs/quality_monitoring.htm
Thank you

Questions?