The PQ (vaccines assessment) process mission, vision, objectives and stakeholders

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Outline

• Concept of vaccine regulation
• Prequalification:
  • Mission, vision and objectives
  • Stakeholders
  • Restructuration
WHO Goal for vaccines regulation

Ensure that “100%” of vaccines used in all national immunization programmes are of assured quality

Definition of “Vaccines of Assured quality”

- National Regulatory Authority (NRA) independent from vaccine manufacturer & procurement system
- NRA is functional (system + 6, 4 or 3 regulatory functions implemented)
- No unresolved reported problem with vaccine

WHO guidance by Experts Committee on Standardization of Biologicals (ECBS) recommendations on safety, efficacy and quality issued in WHO Technical Report Series (TRS)
WHO Concept of Vaccine Regulation

National Regulatory System: Governance + six regulatory functions

1. Marketing Authorization (MA) and Licensing Activities
2. Post-marketing activities including surveillance of Adverse Events Following Immunization (AEFI)
3. NRA Lot Release
4. Laboratory access
5. Regulatory Inspections
6. Authorization/Approval of Clinical Trials
Required functions according to vaccine source

<table>
<thead>
<tr>
<th>Vaccine Source</th>
<th>MAA &amp; licensing</th>
<th>PMS</th>
<th>Lot release</th>
<th>Lab access</th>
<th>Regulatory Inspections</th>
<th>Authorization &amp; monitoring CT</th>
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<tbody>
<tr>
<td>UN agency supply</td>
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<td>Direct purchase</td>
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<td>Producing country</td>
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<td>Exporting country NRA+</td>
<td>All countries where CTs are performed</td>
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Regulatory System
WHO Concept of Vaccine Regulation

Where does the Pre-qualification term come from?

What does it mean?

It is a procurement term

It means limiting a global public tender to fewer than the total universe of possible suppliers.
Prequalification

- From the wider population of vaccines of a certain type select those that meet the required standards of quality, safety and efficacy

- This pre-selection of "eligible" or "acceptable" products leads to the PRE-QUALIFICATION status

- Procurement agencies further qualify the pre-qualified vaccines for purchase based on additional criteria such as:
  - price,
  - lead times for supply,
  - compliance with commitments, etc.
Prequalification Team Mission

Facilitate access to adequate supply of high quality vaccines to member countries
Means to accomplish the mission

Provide advice to UN agencies on the quality, safety and efficacy of vaccines for purchase

By assessing the acceptability, in principle, of vaccines for purchase by Unites Nations Agencies: Vaccines Prequalification Program

By continuous monitoring of quality and compliance with the established specifications
Vision

Build capacity in producing countries raising the standards for production to international levels: support to manufacturers

Build capacity in producing countries by collaborating with the NRAs responsible for the products: support to NRAs

Progressively deposit increased responsibility in NRAs

Phase out the prequalification program
Objectives of the Vaccines PQ program

**MAIN**
- Ensure supply of vaccines of assured Quality through UN agencies
- Vaccines supplied meet WHO Recommendations issued by ECBS for quality, safety and efficacy and UN Tender specifications
- Vaccines supplied meet the needs of the NIPs (programmatically suitable, compatible with the current immunization schedules)

**SECONDARY**
- Replaces regulatory oversight in receiving countries except for Marketing authorization and post-marketing surveillance
- Used as a reference of quality by many countries that procure vaccines directly
- Secure the supply base for vaccines by exploring alternative/additional sources
Prequalification Stakeholders

- Manufacturers and manufacturers' associations
- NRAs in producing countries and NRAs in receiving countries
- UN purchasing agencies
- GAVI
- Other purchasing agencies (MSF, DANIDA, JICS)
- Countries procuring vaccines directly
- Donors
- Immunization programmes
- Programmes for vaccine preventable diseases
PQ restructuring
Role of WHO prequalification

• Facilitate access to safe, appropriate priority diagnostics, medicines & vaccines
• Support two of WHO's six core functions:
  • setting norms & standard/promoting their implementation
  • providing technical support, catalysing change & building institutional capacity.
• Contribute to achieving four of WHO's impact goals:
  • reduce under-five mortality
  • reduce maternal mortality
  • reduce the number of people dying from AIDS, tuberculosis and malaria
  • eradicate polio.
Reorganization: single PQ programme for further impact & restructured regulatory units

Consolidated prequalification programme aiming at:

- **Enhanced management & operations**
  - e.g. quality management system
  - e.g. administrative efficiencies, incl. financial management

- **Better relationship with stakeholders**
  - e.g. single voice when dealing with national regulatory authorities
  - e.g. increased transparency around processes and outcomes

- **Cross-product stream learning**
  - e.g. extension of ERP process to new product categories
  - e.g. bigger pool of external experts and testing laboratories
  - e.g. PQDx benefit from medicines and vaccines experience to improve efficiency

- **Flexibility**
  - transition business-as-usual PQ activities to NRAs
  - WHO PQ moves into new therapeutic areas (e.g. non-communicable diseases) and/or new product types (e.g. biologicals)

Improve regulatory support — pharmacovigilance, norms & standards — to PQ processes
Structure of Department of Essential Medicines & Health Products

- Essential Medicines and Health Product [EMP]
  - Policy, Access and Use [PAU]
  - Regulation of Medicines and other Health Technologies [RHT]
  - Public Health, Innovation and Intellectual Property [PHI]
    - Technologies Standards and Norms [TSN]
    - Regulatory Systems Strengthening [RSS]
    - Prequalification Team [PQT]
    - Safety and Vigilance [SAV]
Structure of the Prequalification Team

Prequalification Team

Coordinator’s office

Vaccines Assessment

Medicines Assessment

Diagnostics Assessment

Inspections

Technical Assistance/Labs

Administrative team