THE WHO PREQUALIFICATION OF IMMUNIZATION DEVICES

ISAAC GOBINA

COPENHAGEN DEC 3 2019
PLAN OF THE PRESENTATION

• HISTORY OF IMD PREQUALIFICATION
• CATEGORIES OF IMDs
• PERFORMANCE SPECIFICATIONS AND VERIFICATION PROTOCOLS
• TARGET PRODUCT PROFILES
• DOSSIER SUBMISSIONS AND EVALUATIONS
• IMD ANNUAL REVIEW AND POST PQ ACTIVITIES
1979 1st printing of equipment performance data as UNICEF SUPDIR55
1979-1985 total of 5 editions of the UNICEF SUPDIR55
1986/87 1st printing of WHO Technical Series - Product Information Sheets
The last hard copy for PIS was printed in 2000
2010 first web based publication
CATEGORIES OF IMD

• E001: Cold rooms, freezer rooms, and related equipment
• E002: Refrigerated vehicles
• E003: Refrigerators and freezers
• E004: Cold boxes and vaccine carriers
• E005: Coolant-packs
• E006: Temperature monitoring devices
• E007: Cold chain accessories
• E008: Injection devices for immunization
• E010: Waste management equipment
• E013: Injection devices for therapeutic purposes
DEVICES FOR THE STORAGE OF VACCINES

• E001: Cold rooms, freezer rooms, and related equipment
• E003: Refrigerators and freezers
DEVICES FOR THE TRANSPORTATION OF VACCINES

• E002: Refrigerated vehicles
• E004: Cold boxes and vaccine carriers
DEVICES FOR THE DELIVERY OF VACCINES AND WASTE DISPOSAL EQUIPMENT

• E008: Injection devices for immunization
• E010: Waste management equipment
• E013: Injection devices for therapeutic purposes
TEMPERATURE MONITORING DEVICES

• E006: Temperature monitoring devices
PERFORMANCE SPECIFICATIONS AND VERIFICATION PROTOCOLS

- **PQS performance specifications**: lay out functional and performance characteristics required of products eligible for PQS prequalification.

- **PQS verification protocols**: ensure products and devices comply with the performance specifications.
A “target product profile” (TPP) is a strategic document that lists the principal desired features of a product category for future PQS prequalification.

TPPs are intended to guide developers and manufacturers, as well as provide advance warning on upcoming specification changes.

TPPs are mostly informed by field-performance feedback, and in addition input from manufacturers and accredited laboratories.
DOSSIER SUBMISSIONS AND ASSESSMENTS
• The **dossier submission process** is straightforward when the dossier is complete and all documents related to the product are in order (required and accompanying).

• When a field evaluation is required for prequalification, the manufacturer must submit a **field evaluation application form** and **evaluation protocol** to the PQS Secretariat for approval before a field evaluation can take place.
DOSSIER ASSESSMENTS

- Product dossiers are currently submitted via email but we aim to have an online submission/tracking portal by 2019.

- Only complete and correct product dossiers are reviewed.

- Complete product dossiers are evaluated on a monthly basis.

- Dossier reviews are carried out by a team of independent evaluators.

Product dossier:
The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Brand name of the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- A comprehensive set of photographs showing all external surfaces of the unit, the interior layout, the compressor and a close-up of the thermometer and the control panel.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer’s ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer’s ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to...
IMD ANNUAL REVIEW AND POST PQ ACTIVITIES

• Once prequalified, a product must be re-evaluated annually to ensure that it continues to be fit-for-purpose.

• Re-evaluation also verifies that manufacturers have maintained their legal status in their countries, and that licenses and certificates are up-to-date.

• The annual re-evaluation exercise takes place on an agreed date each year. All products on the PQS database are assessed, irrespective of the original acceptance date.
POST MARKET MONITORING OF IMDS

• Sentinel surveillance pilot being implemented in 4 countries
  • Democratic Republic of Congo
  • Haiti
  • Bangladesh
  • Pakistan
• Sentinel surveillance in brief:
  • In-country surveillance officer with strong vaccine cold chain background
  • 30-50 sentinel sites per country selected in collaboration with EPI representing the broadest range of cold chain equipment.
  • When equipment failure is reported the surveillance officer together with the local EPI technician, carries out an investigation aimed at determining the root cause of failure
  • Monthly report to national EPI and WHO on a set of PMM indicators and failure analysis
FUTURE PLANS

• QMS AUDITS - 2020
• NEW WEBSITE - 2019
• ONLINE APPLICATION PORTAL – 2021
THANK YOU FOR LISTENING