

# ***WHO PQ programmes***



**World Health  
Organization**

# Programmes

- Vaccines Prequalification
- Pharmaceutical Medicines prequalification
- Diagnostic Test Kits prequalification
- WHO Pesticide Evaluation scheme (WHOPES)



- The purpose of the programmes is to give guidance on which products meet WHO quality standards and specific purchasers' specifications/requirements.
- The products may be procured by UN agencies and other large volume procurers (e.g. the Global Drugs Facility), as well as individual countries.
- WHO prequalification or recommendation may facilitate the registration and use of the evaluated products by the Member States of the WHO and other stakeholders.



- The overall procedural flow of the three prequalification programs is similar.
- There are greater differences compared to the pesticides program but this reflects the differences in product type.



# Pre-submission

- **Identification of Products of Interest**
- Pre-submission steps



# Dossier Submission

## Vaccines:

- custom Product Summary File (PSF) format defined in WHO published documents.
- CTD format data can be presented as supplementary data, cross referenced to PSF chapters.

## ● Pharmaceutical Medicines:

- ICH CTD format is default requirement
- Accepts " a standard dossier in English, as prepared for the national medicines regulatory authorities", cross referenced to the CTD.
- Site Master File

## ● Diagnostics:

- The standard format is a WHO document (PQDx\_018) based on the Global Harmonization Task Force (GHTF) requirements outlined in the Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices. However procedure allows for, "submissions previously prepared for various National Regulatory Authorities provided all the information required by WHO is supplied and the sections of the submitted file are cross-referenced to the WHO format requirements".

## ● Pesticides:

- WHO provides a template for submission of data.



# Sample testing

- Sample testing as part of initial review for all programs
- Post approval testing:
  - Pharmaceuticals and Vaccines: have established testing programs
  - Diagnostics: has developed a post-market surveillance program that is being piloted in 5 countries.
  - Pesticides: no WHO testing but recommendation for national QC testing on consignment receipt.



# Audit of Manufacturers

- Takes place for Vaccines; Pharmaceuticals; Diagnostics
- The function of the audit activity performed by the three prequalification programs is essentially the same, which is to assess activities on the site against appropriate standards:
  - Vaccines and Pharmaceuticals: WHO GMP guidelines
  - Diagnostics program assesses manufacturers according to the ISO 13485 and other relevant ISO standards and Global Harmonization Task Force (GHTF) guidelines.





# Reporting Process

- All programmes issue reports of the review to the manufacturer, who is able to submit responses for review, as required.
- All programmes list prequalified/recommended products on WHO websites.



# Complaints

- Pharmaceuticals and Vaccines have procedures in place for complaint investigations.
- A complaints procedure is under development in the Diagnostics program.



# Reassessment

- Vaccines: Reassessment period for vaccine prequalification is currently between 2 years to 5 years dependent on experience with manufacturer and vaccine type but proposals regarding this are in the new draft of the procedure.
- Pharmaceuticals: Re-inspections are conducted approximately every 2 years and products are re-qualified every 5 years.
- Diagnostics: 3 year maximum interval proposed
- Pesticides: No set period for reassessment.
- Complaints as a trigger for reassessment



# Variation to Process

- A different process for pharmaceuticals manufactured under the control of a "stringent regulatory authority" (SRA)- both for innovator and generic pharmaceuticals
- Diagnostics: If products are assessed by SRA (defined as Global Harmonization Taskforce [GHTF] member states), extent of WHO assessment is dependent on degree of in-country assessment (eg for export only products) and includes suitability for use in resource limited settings
- Vaccines: Draft revised procedure [http://www.who.int/immunization\\_standards/vaccine\\_quality/pq\\_revision2010/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/pq_revision2010/en/index.html) includes : Considerations for streamlining the prequalification procedure based on enhanced assistance by NRAs
- Pesticides: there is an abbreviated procedure by which additional manufacturers of a pesticide for which there is an existing recommendation may apply for an extension of the specification to include their product

# Interaction with the NRA

## Vaccines

- Precondition for submission of an application, is that the country of manufacture has an NRA that has been assessed as functional by the WHO for regulation of vaccines and that the product has been licensed by the NRA.
- Agreement with NRA in country of manufacture on NRA's role in post-PQ monitoring of the product.



# Capacity development

## Vaccines

- Requirement for functional NRA in country of manufacture for prequalification
- Participation of NRA representatives in PQ site audits
- NRA strengthening programme including formulation of Institutional Development plans
- Global Learning Opportunities for Vaccine Quality
- Support for DVCRN and AVAREF for strengthening regulatory oversight of clinical trials of vaccines.



# Capacity development

## Pharmaceuticals

- procedure indicates that WHO may collaborate with national medicines regulatory authorities in the quality assessment. Applicants are recommended to advise the NRA in the country of manufacture of their submission for prequalification and request the authority to collaborate with WHO in the assessment.
- Participation of NRA representatives in PQ site audits
- Assistance can be provided via expert consultants to Manufacturers; Quality Control Laboratories and Regulators, focuses on – GMP, GCP or GLP compliance and regulatory guidance
  - This is separated from the assessment / inspection process



# Capacity Development

## Diagnostics

- NRA representatives as observers in dossier assessments and site inspections
- Five Country Project - 3 years (Tanzania, Cote d'Ivoire, Burkina Faso, RSA, China)
  - capacity building of regulation, post market surveillance of diagnostics (including laboratory capacity building)
- Training / workshops
  - regulation, post market surveillance (including batch testing pre and post market distribution)

