Session 2: Overview of the WHO Prequalification Programme

World Health Organization

UNFPA

PATH
A catalyst for global health

Prequalification

- In principal: A documented process for reviewing a product or service to ensure it complies with identified criteria

  WHO – Prequalification is focused on criteria relevant for public health: quality, safety, efficacy, and performance

- Supplier qualification systems differ in the level of product evaluation performed

- Workshop is focused on the WHO Prequalification Programme for Priority Medicines and Prequalification of Condoms and IUDs (UNFPA)

Other Prequalification Systems

- WHO Prequalification Programme for Vaccines
- WHO Prequalification Programme for HIV diagnostics
- WHO/UNICEF Prequalification Programme for Immunization Products
- WHO Prequalification Programme for Quality Control Laboratories
- Independent procurement organizations (e.g., International Dispensary Association and Missionpharma)

WHO Prequalification Programme for Medicines

- Originally the Prequalification Programme for Priority Medicines, including: HIV/AIDS, Tuberculosis, and Malaria medicines
- Expanded to include reproductive health medicines, and condoms and intrauterine devices (IUDs) with UNFPA

Product Prequalification

- Evaluation of product information including APIs, formulation, manufacture, quality control, and test results
- Inspection and verification of data:
  - GCP (Good Clinical Practice)
  - cGMP inspections (current Good Manufacturing Practice)
- Monitoring: Ongoing monitoring, variations, re-qualification, and de-listing of products

Essential Steps: Medicines

- Expression of interest (EOI) is published
- Interested parties submit dossiers
- Dossiers receive initial screening
- Full dossier assessment
- Site inspections are conducted
- Report on findings and recommendations is released
- Evaluation results are published

Essential Steps: Monitoring Medicines

Ongoing monitoring after initial prequalification:

- Sampling and testing
- Reevaluation
- Reinspection
- De-listing (if and when appropriate)

UNFPA Prequalification Programme for Condoms and IUDs

Background:

- UNFPA began its product prequalification process in 2001
- Prequalification focuses on suppliers of condoms and IUDs
- UNFPA and WHO are harmonizing prequalification processes for condoms and IUDs

Prequalification for Condoms and IUDs

- Existing process based on UNFPA programme
- Process is essentially similar to process for medicines, with some exceptions:
  - Submission and evaluation of key documents versus dossier
  - Pre-shipment sampling is a requirement for condoms

Benefits of Using the WHO and UNFPA Prequalification Programmes

Small Group Exercise

Instructions to participants:

1. Work in groups of three to five people.
2. Discuss the benefits of using the WHO and UNFPA Prequalification Programmes. Brainstorm an extensive list, then discuss with the group members. The space on this page below is provided for your personal notes.
3. Select the top three benefits – ones that you think are more important or significant than the others. List these on a piece of flipchart paper.
4. Take no more than 20 minutes for discussion in your small group.
5. Assign a spokesperson to report out to the larger group.

Discussion question:

- What are the benefits of using the WHO and UNFPA Prequalification Programmes?

A related question for discussion might be:

- How could a prequalification system support your country's national regulatory agency?

Brainstorm of benefits:

Select the top three most important ones:

Prequalified Medicines
Answer Key to Exercise

Instructions to participants:

1. Work in groups of 3–5 people.
2. Review the list of the Prequalification Programme's Priority Essential Medicines – Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality distributed to you by the facilitators.
3. Work together with your group to answer as many of the questions below as possible. You have approximately 15 minutes for this exercise.
4. After the exercise, an answer sheet will be distributed and you will have approximately 5–10 minutes to review and discuss with your group.

1.	How many manufactures are prequalified to produce Nevirapine?	**7**
2.	Name two medicines from these prequalified medicine lists that are included on your country's essential medicines list or are priorities for procurement.	**(Multiple answers)**
3.	In what country is the prequalified manufacturer of Abacavir Surlfate based?	**India**
4.	Is there a prequalified manufacturer of Stavudine based in South Africa?	**Yes – Aspen**
5.	In what country is the medicine Ganciclovir manufactured?	**Switzerland**
6.	Name four medicines manufactured in India.	**(Many examples)** Abacavir, Aciclovir, Nevirapine, Cycloserine
7.	Name one medicine that comes in capsule, tablet, infusion, and solution forms.	**Zidovudine**
8.	What are the three dosages available for Aciclovir dispersable tablets?	**200, 400, and 800 mg**
9.	Name two medicines that are manufactured by Cipla in Goa, India.	**Lamivudine, Nevirapine**
10.	Does Fluconazole come in pill form?	**No – capsules**
11.	Is Lamivudine available as an oral solution?	**Yes – 10 mg**
12.	Which medicine has the largest number of prequalified manufacturers?	**Lamivudine – 8** **Stavudine - 8**
13.	Name two medicines that you order from your country's essential medicines list that are not listed on these prequalification lists.	**(Multiple answers)**