Session 11:
WHO Prequalification Programme Website

World Health Organization

UNFPA

PATH
A catalyst for global health

PREQUALIFICATION PROGRAMME - PRIORITY ESSENTIAL MEDICINES
A United Nations Programme managed by WHO

- The Prequalification Programme was created by the World Health Organization in 2001. It aims to increase access to priority medicinal products that meet unified standards of acceptable quality, safety and efficacy, currently focusing on those used for HIV/AIDS, Malaria, Tuberculosis and for Reproductive Health.

- The Programme undertakes comprehensive evaluation of the quality, safety and efficacy of medicinal products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing and clinical sites. The Programme also prequalifies quality control laboratories of pharmaceuticals.

- Since the Programme's inception, capacity building and training of staff from national regulatory authorities, quality control laboratories, and from manufacturers or other private companies, have been major activities.

- The list of prequalified medicinal products is used principally by United Nations agencies - including UNAIDS and UNICEF - to guide their procurement decisions. But, the list has become a vital tool for any agency or organization involved in bulk purchasing of medicines, be this at country level, or at international level, as demonstrated by the Global Fund to Fight AIDS, Tuberculosis and Malaria.

LATEST NEWS

Suspension of Viracept from the list of WHO prequalified products

WHO Statement on Roche's Viracept® recall

Déclaration de l'OMS concernant le rappel du produit Viracept® du laboratoire Roche

Declaración de la OMS sobre la retirada de Viracept® Roche

All News

QUICK LINKS

HIV/AIDS Prequalified Products (PDF)

Malaria Prequalified Products (PDF)

TB Prequalified Products (PDF)

7th EOI Invitation for HIV products

QC Laboratories (PDF)

WHO Public Assessment Reports: WHOPARs

Information for applicants

General information

- General Procedure [pdf]
- How to participate in the Prequalification
  - HIV/AIDS - 7th Invitation for Expression of Interest (EOI) [pdf]
  - Malaria - 4th Invitation for Expression of Interest (EOI) [pdf]
  - TB - 6th Invitation for Expression of Interest (EOI) [pdf]
  - Reproductive Health - 1st Invitation for Expression of Interest (EOI) [pdf]
- Where to send
  - the Dossier
  - the Site Master File (SMF)
- Information on Dossier assessments
- Information on Inspections

Prequalification Guidelines

- Medicinal Products
- Quality Control Laboratories
- Confidentiality

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Information for Users

Information for Regulatory Authorities

This section is currently under revision.

Information for Buyers

When purchasing of products from the list, any procurement agency using the list of products and manufacturers that meet WHO norms and standards, should make sure that:

- The most current edition of the list is used
- The contracted manufacturer will supply the product as was prequalified in all aspects in the product dossier (including at least specifications, Active Pharmaceutical Ingredient, formula, manufacturing method etc) that was assessed by WHO.
- The product supplied by the manufacturer, was manufactured in the site as listed in the product dossier assessed by WHO and inspected by WHO (as appearing on the list).

WHO recommends that procurement agencies enter into an agreement or contract with the manufacturer prior to purchasing of products. Responsibilities of each party should be clearly defined in the agreement including reference to the above-mentioned aspects.

The agreement should make provision for liability and remedies in case of breach of contract.
If you purchase products using this list, please provide the following information to WHO; by email or fax:

Name, address and contact details of your organization			
Products purchased	Product number on list	Quantity purchased	Batch number

Information for Procurement Agencies

- Detailed information for Procurement agencies

Information on Dossier Assessments and Inspections

A manufacturer wishing their medicinal products to be included in the prequalified products list must submit extensive information on the product (or products) to allow qualified teams of assessors to comprehensively evaluate its quality, safety and efficacy. The manufacturer must also open its manufacturing and clinical sites to an inspection team to assess compliance with WHO Good Manufacturing Practices (GMP) and WHO Good Clinical Practices (GCP) and Good Laboratory Practices (GLP), respectively.

Dossier assessments

A team of assessors evaluates all the data presented in each part of the dossier (Quality and Efficacy/Safety). When both parts of the dossier are judged as being in compliance with the Prequalification Programme guidelines the dossier will be accepted.

The list of product dossiers currently under scientific evaluation in the Prequalification Programme:

- Status of dossier assessments

Inspections

Only manufacturers and Contract Research Organizations (CROs) meeting GMP and GCP/GLP requirements are included in the list below. Prior to listing, all the critical, major and other observations listed in the inspection report must be addressed and brought to a satisfactory level of compliance by the manufacturers.

- Inspections - List of inspections performed and Outcomes

The WHO Public Inspection Report (WHOPIR) reflects the inspection report and gives a summary of the observations and findings made during the inspection, but excludes confidential proprietary information. It also indicates the date and duration of the inspection as well as the scope of the inspection.

- WHOPIRs

Prequalification of a product

When both the product dossier and all relevant manufacturing and clinical sites have been found acceptable the product can be prequalified and listed on the Prequalification Programme website, together with the applicant's name and the corresponding manufacturing site of the finished product.

The purpose of the WHO Public Assessment Report (WHOPAR) is to provide all interested parties with transparent access to information on the procedure followed for the assessment of a pharmaceutical product, which has been prequalified. In addition, the

Training material and workshops

The following is a collection of WHO/QSM training packages and various resources from workshops and seminars.

Good manufacturing Practices (GMP) Training modules

- GMP training modules (basic and supplementary training)

Quality Control Training modules

- Training modules

Upcoming Training Events

WHO Prequalification Programme Meeting on Priority Essential Medicines

- **Cairo, Egypt**
  6 - 7 June 2007
  Details [pdf]
  Programme [pdf]

Workshops and seminars

WHO/FIP Training Workshop on Pharmaceutical Development with a Focus on Paediatric Medicines

- **Cape Town, South Africa**
  16 - 20 April 2007
  Details [pdf]
  Programme [pdf]
  Presentations [ppt]

Training Workshop on Pharmaceutical Quality, Good Manufacturing Practice and Bioequivalence with a Focus on Artemisinines

- **Dar-es-Salam, United Republic of Tanzania**

Press and Media

Prequalification updates - see also: WHO Media centre

PQ Update - June 2007	**New WHO Public Inspection Report (WHOPIR)** published on the Prequalification Programme web site.
PQ Update - June 2007	**2 new WHO Public Inspection Reports (WHOPIRs)** published on the Prequalification Programme web site.
PQ Update - June 2007	WHO Prequalification Programme issues **new (7th) Invitation for Expression of Interest (EOI) for HIV medicinal products.**
PQ Update - June 2007	WHO Prequalification Programme adds **new product to its List of Prequalified HIV/AIDS Medicines. New WHO Public Assessment Report (WHOPAR) published.** New WHOPAR marked in red on Table
PQ Update - May 2007	**5 New Products added** to WHO Prequalification Programme List of Prequalified HIV/AIDS Medicines
PQ Update - May 2007	**8 New WHO Public Assessment Reports** published. New WHOPARs marked in red on WHOPAR List.
PQ Update - April 2007	**Annual Report of the Prequalification Programme 2006** English | French
PQ Update - 13 April 2007	**New CIPLA manufacturing site added** to 51st Edition List HIV/AIDS of Prequalified Products & Manufacturers.
PQ Update - 13 April 2007	**Ranbaxy withdraws anti-infectives** from prequalified products list.
PQ Update - 23 March 2007	**4 New Products added** to WHO Prequalification Programme List of Prequalified Tuberculosis Medicines
PQ Update - 19 Feb 2007	**10 New WHO Public Assessment Reports** posted. New WHOPARs marked in red on WHOPAR List.
PQ Update - 14 Feb 2007	**New CIPLA manufacturing site added** to 48th Edition List HIV/AIDS of Prequalified Products & Manufacturers.
PQ Update - 01 Dec 2005	WHO **adds more new products** to its list of prequalified medicines

Demonstration

- www.who.int/prequal