Prequalification project:
Ensuring the quality, safety and efficacy of HIV/AIDS, tuberculosis and malaria medicines and diagnostics

Bi-regional Workshop on the Management of Antiretroviral Medicines
Phnom Penh, Cambodia, 13-16 December 2004
Why we need prequalification

➔ It offers equal opportunities for manufacturers from all countries to comply with international standards and participate in solving health emergencies
➔ It vastly reduces the risk of sourcing sub-standard, counterfeit and/or contaminated medicines
➔ It speeds up access to quality medicines using an efficient, standardized evaluation process
➔ It facilitates a fast contract award process through limited invitations for competitive bidding
How are medicines prequalified?

→ Prequalification begins with an Expression of Interest from a prospective supplier.
→ The product dossier is evaluated according to published standards set by WHO and partners
→ Manufacturing sites are inspected to assess compliance with GMP
→ Working as a team put together by WHO, international experts perform product assessments and inspect manufacturing sites
  • Both product AND manufacturing site have to meet the required standards to be added to the list of prequalified products
→ Samples are tested for compliance with specifications
  • Samples are also taken from supplied batches
→ Products are requalified after 3 years
How are medicines prequalified?

- Generic manufacturers must offer data on:
  - Active Pharmaceutical Ingredient
  - Specifications
  - Product formula
  - Manufacturing method
  - Stability
  - **Bio-equivalence**

- Innovator products require:
  - WHO-type Certificate of a Pharmaceutical Product
  - Assessment report issued by the respective regulatory authority
  - WHO-type batch certificate from the manufacturer
Strengths of the PQ process

- It is rigorous but efficient
- It builds local regulatory and production capacity
- It includes ongoing monitoring
- It provides innovator companies with a fast-track process
- It provides a positive list of prequalified products and manufacturers
- It gives assurance that international quality standards have been applied
Who are involved in prequalification?

- The project is managed by WHO in partnership with UNICEF, UNAIDS and UNFPA and is supported by the WB.
- Technical assistance comes from experts from national medicines regulatory authorities from more than 20 countries (including India, Indonesia, Malaysia, the Philippines and Thailand).
What has been achieved so far?

- Listing of prequalified HIV/AIDS medicines and manufacturers
  - 21\textsuperscript{st} Edition was published on 30 November 2004
- Model quality assurance system developed
- Country capacity to produce good quality ARVs enhanced
- Improved developing country regulatory capacity to assess ARVs
- Greater international cooperation on medicines quality
- More efficient procurement and quality control strategies
Recent problems.....

De-listings and voluntary withdrawals

- Specific Contract Research Organizations (CROs) were found to be non-compliant with international guidance on Good Clinical Practice (GCP) and Good Laboratory Practice (GLP)
- Bioequivalence with the originator product was therefore no longer proven
- The manufacturers concerned indicated that they would have the bioequivalence studies redone
- WHO and its partners agreed to reassess and inspect new submissions of previously de-listed or withdrawn products as a matter of urgency

- The first "re-listings" took place on 30 November 2004

Campaigning by "interest groups"
Welcome to the web site of the Prequalification project managed by the World Health Organization (WHO)

Follow the quick links below for general information on the prequalification of products and manufacturers, focusing on HIV/AIDS, Tuberculosis and Malaria.

For any technical enquiries related to the Prequalification Project Web Site, please contact us by email: grffng@who.int
HIV/AIDS

List of prequalified products and manufacturers

Procurement, Quality and Sourcing Project: Access to HIV/AIDS Drugs of Acceptable Quality

NOTE:
ALL DOCUMENTS LINKED TO THIS PAGE ARE UNEDITED AND IN DRAFT FORMAT - UNLESS STATED OTHERWISE. COMMENTS AND RECOMMENDATIONS CAN BE SUBMITTED TO THE CONTACT PERSONS LISTED BELOW.

About the project...

WHO, UNICEF, UNAIDS and many other international, regional and national organizations are involved in procuring drugs. The supply of drugs for HIV/AIDS, malaria and TB in particular, has become a major concern at both international and country level. Recent commitments by the European Commission and G8 countries, among others, offer the potential for significant increases in funding for efforts to combat communicable diseases. Low-cost drugs of assured quality have the greatest potential for maximizing the impact of these efforts.

In addition, recent efforts to accelerate access to HIV-related drugs through negotiation and generic competition have highlighted the importance of quality assurance for procurement of drugs and diagnostics.
Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality

Procurement, Quality and Sourcing Project

MANUFACTURERS AND SUPPLIERS WHOSE HIV-RELATED MEDICINES HAVE BEEN FOUND ACCEPTABLE, IN PRINCIPLE, FOR PROCUREMENT BY UN AGENCIES.

Date: 30 November 2004

This list is the 21st Edition. The list is regularly updated and each change on previous version is labelled in blue. Kindly ensure that the most current list is used. For changes to the list, see Table 1: Version history (below the "List")

List : Alphabetical list of prequalified products manufactured at the specified manufacturing sites

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>International Non-proprietary Name (INN)</th>
<th>Strength</th>
<th>Dosage form</th>
<th>Supplier</th>
<th>Manufacturing site</th>
<th>Packaging material and pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>106</td>
<td>Abacavir</td>
<td>300mg</td>
<td>Tablet</td>
<td>GlaxoSmithKline</td>
<td>Ware, Hertfordshire, UK</td>
<td>Blister 60</td>
</tr>
<tr>
<td>107</td>
<td>Abacavir</td>
<td>20mg/ml</td>
<td>Oral solution</td>
<td>GlaxoSmithKline</td>
<td>Speke, Liverpool, Mississauga, Ontario, UK</td>
<td>HDPE bottle 240ml</td>
</tr>
<tr>
<td>040</td>
<td>Aciclovir</td>
<td>200mg</td>
<td>Dispersable tablet</td>
<td>Cipla Ltd</td>
<td>Patalganga, India</td>
<td>Blister 10</td>
</tr>
<tr>
<td>045</td>
<td>Aciclovir</td>
<td>400mg</td>
<td>Dispersable tablet</td>
<td>Cipla Ltd</td>
<td>Patalganga, India</td>
<td>Blister 5</td>
</tr>
<tr>
<td>046</td>
<td>Aciclovir</td>
<td>800mg</td>
<td>Dispersable tablet</td>
<td>Cipla Ltd</td>
<td>Patalganga, India</td>
<td>Blister 5</td>
</tr>
</tbody>
</table>
For more information on the prequalification project please visit

http://mednet3.who.int/prequal/

"With technical input and guidance, manufacturers of generic medicines in developing countries are able to manufacture ARVs of proven quality and efficacy"