Session 13:

Prequalification Within the Context of Global Fund Procurements

World Health Organization

UNFPA

PATH
A catalyst for global health

Global Fund

- Established in 2002
- Attracts and disburses additional resources to prevent and treat AIDS, tuberculosis (TB), and malaria
- Six funding rounds to date
- $7.74 billion approved
- 450 grants to 136 countries

Global Fund Quality Assurance Requirements

Funds used in Global Fund procurement must meet the following quality standards:

- Product is acceptable under the WHO Prequalification Programme, or
- Product is authorized for use by a stringent regulatory authority, or
- Product is manufactured under a WHO or stringent regulatory authority's current good manufacturing practices (cGMP), with conditions
- Standard C is a Global Fund option, but is not endorsed or recommended by WHO

http://www.theglobalfund.org/en/about/procurement/quality/

Standard A:
Prequalified by WHO

- Product is listed as prequalified under the WHO Prequalification Programme

Standard B:
Stringent Regulatory Authority

Product is authorized for use by a stringent regulatory authority in ICH or PIC/S member country:

ICH = International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

- PIC/S = Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

http://www.theglobalfund.org/pdf/guidelines/List_of_Countries_ICH_PICS.pdf

PIC/S and ICH Countries

PIC/S Countries		ICH Countries	
Australia	Liechtenstein	Austria	Lithuania
Austria	Malaysia	Belgium	Luxembourg
Belgium	Netherlands	Cyprus	Malta
Canada	Norway	Czech Republic	Netherlands
Czech Republic	Poland	Denmark	Poland
Denmark	Portugal	Estonia	Slovakia
Finland	Romania	Finland	Slovenia
France	Singapore	France	Spain
Germany	Slovak Republic	Germany	Sweden
Greece	Spain	Greece	United Kingdom
Hungary	Sweden	Hungary	United States
Iceland	Switzerland	Ireland	
Ireland	South Africa	Italy	
Italy	United Kingdom	Japan	
Latvia		Latvia	

Requirement for Standards A and B

- If two or more suppliers, for which standard A or B applies, can supply the required product within 90 days of order, then the product **must** be procured from this set of manufacturers (from Standard A or B)

- If not, may request to use standards C1 or C2

Standard C

- If A and B are not possible, the Global Fund allows for the following options:

  -C1: Suppliers who have submitted for prequalification and who have WHO/SA cGMP; or

  -C2: Suppliers who have not submitted for prequalification and who have WHO/SA cGMP

- Requires concurrence and testing, arranged independently by the Global Fund Secretariat

- WHO does not recommend or endorse this option, but acknowledges that there may be situations where such options may be necessary

PIC/S and ICH Countries with Stringent Regulatory Authorities
July 2007

PIC/S

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive cooperation in the field of GMP. PIC/S' mission is **"to lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products."** This is to be achieved by developing and promoting harmonized GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates; and facilitating the cooperation and networking for competent authorities and international organizations.

PIC/S participating regulatory authorities (www.picscheme.org):

Australia	Austria	Belgium	Canada
Czech Republic	Denmark	Finland	France
Germany	Greece	Hungary	Iceland
Ireland	Italy	Latvia	Liechtenstein
Malaysia	Netherlands	Norway	Poland
Portugal	Romania	Singapore	Slovak Republic
Spain	Sweden	Switzerland	South Africa (July 07)
United Kingdom			

ICH

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of such harmonisation is a more economical use of human, animal, and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.

ICH participating regulatory authorities (www.ich.org):

European Union*
Japan
United States

* Members include: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Slovakia, Slovenia, Spain, Sweden, the Netherlands, United Kingdom

Prequalification Within the Context of Global Fund Procurements
Resource Materials

- Manufacturers and Suppliers whose HIV-Related Medicines Have Been Found Acceptable, in Principle, for Procurement by UN Agencies. WHO Prequalification Programme. http://healthtech.who.int/pq/lists/hiv_suppliers.pdf

- Global Fund Quality Assurance Policy. Global Fund. http://www.theglobalfund.org/pdf/guidelines/QA_Board_Decision_2007.pdf

- Frequently-Asked Questions (FAQs) about Quality-Control Testing of Pharmaceutical Products Used in the Prevention and Treatment of HIV/AIDS, Tuberculosis and Malaria to be Purchased with Global Fund Resources. Global Fund. http://www.theglobalfund.org/pdf/guidelines/QCTestingPharmaceuticalProducts.pdf

- Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries. Médecins Sans Frontières. http://www.accessmed-msf.org/fileadmin/user_upload/diseases/hiv-aids/Untangling_the_Web/UTW10_RSep_horizontal.pdf

- International Drug Price Indicator Guide. MSH. http://erc.msh.org/dmpguide/pdf/DrugPriceGuide_2007_En.pdf