

Session 1:

Prequalification and Procurement



World Health
Organization



Session Objectives

- Discuss aims of the World Health Organization (WHO) Prequalification Programme
- Explain the role of the United Nations Population Fund (UNFPA) in condom prequalification and procurement
- Understand benefits to prequalification
- Discuss changing trends among procurement bodies
- Identify factors that enable successful prequalification

Prequalification

WHO Prequalification Programme for Medicines and Devices

The WHO Prequalification Programme can assist countries as they increase capacity to:

- Ensure high-quality commodities
- Access generic medicines and low-cost devices
- Help to keep costs low
- Reduce the number of inspections/audits
- Harmonize quality standards to support pooled procurement
- Ensure safety and efficacy throughout shelf life

Trend Toward Use of Prequalification by Procurement Agencies

- Global Fund
- Roll Back Malaria Partnership
- Stop TB Partnership
- Clinton Foundation
- World Bank
- UN agencies

Basic Principles of WHO Prequalification Programme

- Voluntary
- Legitimate
- Widely discussed
- Transparent
- Open to both innovator drugs and multi-source generic manufacturers

Aims of WHO Prequalification Programme for Condoms

- Ensure that products are safe and effective throughout stated shelf life
- Ensure that manufacturers have effective quality management systems
- Ensure that condoms are tested to meet the requirements of respective product standards

Aims of WHO Prequalification Programme for Condoms

(continued)

- Determine the physical capacity of manufacturers to deliver required quantities of condoms
- Enhance confidence in ability of manufacturers to meet all requirements and reduce the level of associated risk
- Save time and resources in identification of reliable manufacturers

UNFPA Role in Prequalification

- WHO has delegated UNFPA to manage the prequalification of condoms and intrauterine devices
- UNFPA aims to evaluate all suppliers that express interest
- UNFPA and WHO are harmonizing the prequalification process of devices and medicines

Advantages of Prequalification for Manufacturers

- Eligible to bid for UNFPA procurement
- Acceptance as a qualified bidder as public-sector procurement bodies, governments, and nongovernmental organizations (NGOs) move toward prequalification requirements
- Fewer inspections per factory

Advantages of Prequalification for Manufacturers

(continued)

- Reduced time and expense from responding to different inspectors and prequalification schemes
- Potential for increased sales as more donors and procurers require prequalification
- At present, there is no cost for participating in prequalification process

Limitations of Prequalification for Manufacturers

(continued)

- Intended for primary male latex condom manufacturers only
- Does not guarantee business
- Is an ongoing process
- Products are still subject to pre-shipment compliance testing and inspection

Benefits of Prequalification

- For procurers, governments, and NGOs:
 - Saves time, resources, and costs in finding reliable manufacturers
 - Assures that products consistently comply with ISO standards and WHO specifications
- For users:
 - High-quality, affordable condoms
 - Effective throughout stated shelf life
 - May be less expensive

Prequalification Experiences

Group Questions:

- What factors contributed to your company's success in becoming prequalified?
- What factors, if any, have made it difficult to achieve prequalification?
- What issues do companies need to consider before seeking prequalification?
- Other issues?

Procurement

UNFPA Role in Procurement

- UNFPA is the major procurer of contraceptives in the UN family
- UNFPA purchases contraceptives for UNFPA programmes
- UNFPA also acts as a procurement agent for other authorities, including governments

UNFPA Procurement Services

- Integral part of our work in support of UNFPA programmes
- Viewed as a strategic competitive advantage
- Volumes growing with time
- Transparent and fair processes
- Lead agency in reproductive health commodities
- Can also act as a procurement agency

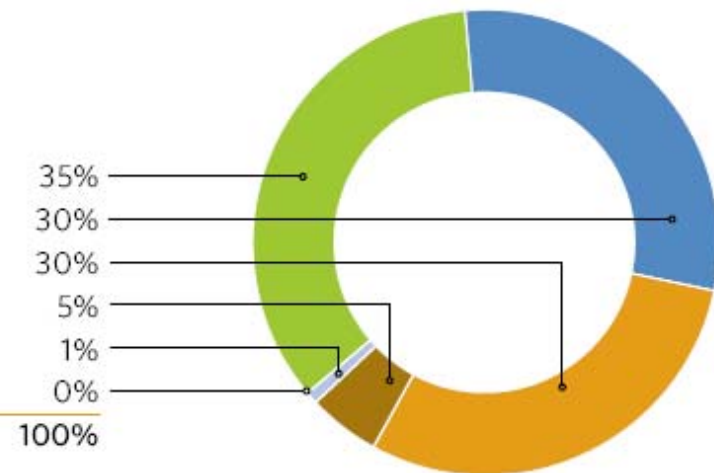
UNFPA's Contraceptive Purchases: 2006

Contraceptive Distribution

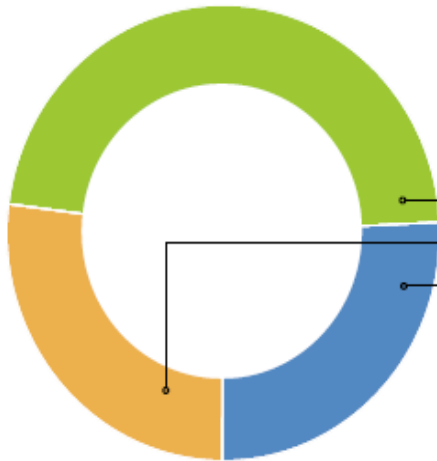
Relative Expenditure versus individual contraceptive methods

US\$

25,832,453	Injectables (incl. syringes and needles)
22,413,646	Pills
22,122,982	Condoms (incl. male and female)
3,348,750	Implants/Trocars
567,346	IUDs
82,381	Spermicides
<hr/> 74,367,557	<hr/> Total



Sources of Commodities



Country Distribution

Source of Procurement

US\$		
98,771,785	Developing Countries	47%
56,105,127	Major Donor Countries	27%
53,503,128	Developed Countries	26%
208,380,038	Total	100%

Purchasing Policy

- Since 2001, UNFPA has issued condom contracts only to prequalified manufacturers

Why the Increasing Trend Toward Prequalification?

Driven by recognition of:

- Need to bring additional suppliers to the market to increase product supply and promote competition
- Need to ensure an adequate level of product quality
- Increased decentralized funding requiring more national procurement
- Varying capacity of national regulatory authorities (NRAs) to manage product QA

National Procurement

- National governments have an increased responsibility to:
 - Forecast
 - Finance
 - Procure and distribute
 - Maintain the quality of products
- They may still use UNFPA for procurement

Reliance on Prequalified Suppliers

- All purchasing bodies will have access to lists of prequalified manufacturers
- Only prequalified manufacturers will be invited to tender
- Purchasers will be able to guarantee quality and simplify their purchasing procedures

Questions?

Website References

WHO Prequalification Programme Website

- WHO website: <http://www.who.int>
- WHO Prequalification Programme website: <http://mednet3.who.int/prequal>
- Websites include:
 - Information for applicants
 - Information for other users
 - Invitations for Expressions of Interest (EOIs)
 - Status of dossier assessments and inspections
 - Training material, workshops, and meetings

UNFPA Procurement Website

- UNFPA website: <http://www.unfpa.org>
- UNFPA Procurement website: <http://www.unfpa.org/procurement>
- Websites include:
 - Information on procurement services
 - Information on clients
 - Information on suppliers
 - Current bids
 - Invitation to prequalify
 - Feedback

UN Global Marketplace

- United Nations website: www.Ungm.org
- Information about:
 - Supplying to the UN
 - Supplier Registration
 - UN procurement
 - Contract awards

Donors and Programs Endorsing the WHO Prequalification Programme

Global Fund

The Global Fund to Fight AIDS, Tuberculosis, and Malaria was created to dramatically increase resources to fight three of the world's most devastating diseases—HIV/AIDS, tuberculosis (TB), and malaria—and to direct those resources to areas of greatest need. The Global Fund is a partnership between governments, civil society, the private sector, and affected communities.

The Global Fund's original procurement policy allowed for three options in procuring single- or limited-source pharmaceutical products (products for which there are no public monographs for finished dosage form in the International, British, or US pharmacopoeia). These options were the two identified here:

- WHO prequalified product
- Product authorized by a stringent regulatory authority. A stringent regulatory authority is defined as a national regulatory authority participating in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) or the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

A third option to procure products approved by the NRA of the recipient country expired in 2005 and is no longer available.

Roll Back Malaria Partnership

The Roll Back Malaria (RBM) Partnership was established in 1998 by the WHO, the United Nations Children's Fund (UNICEF), the United Nations Development Program (UNDP), and the World Bank to provide a coordinated global approach to fight malaria. Since then, the RBM Partnership has expanded to include a wider range of partners—including malaria-endemic countries, bilateral and multilateral development partners, the private sector, nongovernmental and community-based organizations, and foundations.

Partners are working together to scale up malaria-control efforts at the country level, to coordinate their activities to avoid duplication and fragmentation, and to ensure optimal use of resources.

A key role of the RBM Partnership is to lead continuing advocacy campaigns to raise awareness of malaria at the global, regional, national, and community levels.

The RBM does not procure malaria commodities. UNICEF provides procurement services in support of RBM and is the world's largest buyer of mosquito nets. All mosquito nets procured by UNICEF must comply with the WHO pesticide evaluation scheme and all anti-malarial medicines must be WHO-prequalified.

Stop TB Partnership

The Stop TB Partnership was established in 2000 to realize the goal of eliminating TB as a public health problem. It comprises a network of more than 500 international organizations, countries, donors from the public and private sectors, and nongovernmental and governmental organizations that have expressed an interest in working together to achieve this goal. WHO is a partner in the Stop TB Partnership, as is the Global Drug Facility (GDF).

The GDF is a mechanism to expand access to, and availability of, high-quality anti-TB medicines and diagnostics to support the Stop TB Strategy. The GDF both supplies donated medicines and procures medicines to support national TB programs. GDF offers a standardized WHO-approved catalog of anti-TB medicines and formulations designed to promote the products prioritized by the WHO Stop TB department.

All medicines supplied by the GDF must be WHO-prequalified or reviewed and approved by a committee of independent experts pending WHO prequalification.

Clinton Foundation

The mission of the Clinton Foundation is to strengthen the capacity of people throughout the world to meet the challenges of global interdependence. To advance this mission, the Clinton Foundation has developed programs and partnerships in the following areas:

- Health security
- Economic empowerment
- Leadership development and citizen service
- Racial, ethnic, and religious reconciliation

In 2003, the Clinton Foundation HIV/AIDS Initiative announced an agreement with five suppliers of generic antiretroviral (ARV) medications to dramatically cut the price of the most commonly used triple medicine therapy combinations for HIV/AIDS.

The Clinton Foundation's quality standard mirrors the global fund requirements. The Foundation "is committed to the sustainable supply of high-quality ARVs, consistent with the specifications of dossiers approved by the World Health Organization or a stringent regulatory authority such as the USFDA" (Source: www.clintonfoundation.org).

75 percent of the medicines in the Clinton Foundation agreement are individual formulations and two- and three-medicine fixed-dose combinations that have been prequalified or have been submitted for prequalification to WHO.

World Bank

While the World Bank does not limit its funded projects to procuring only WHO prequalified products, it strongly supports the WHO Prequalification Programme as evidenced by statements and requirements in its published documents.

The World Bank recognizes that not all countries have the capacity to conduct a valid product prequalification process. In its publication “HIV/AIDS: A Decision Maker’s Guide to Procurement of Medicines and Related Supplies,” the World Bank strongly recommends that in those circumstances, WHO-prequalified HIV/AIDS medicines should be procured.

In the World Bank’s recent announcement of its partnership with the Global Fund, Clinton Foundation, and UNICEF, the Bank announced that its quality standard for ARVs purchased under this partnership would be the same as the Clinton Foundation (i.e., prequalified by WHO or a stringent regulatory authority).

The World Bank also depends on WHO standards for malaria diagnostic test kits and bed nets approved by the WHO pesticide evaluation scheme.