Session 2:

Overview of the WHO Prequalification Programme for Condoms

World Health Organization

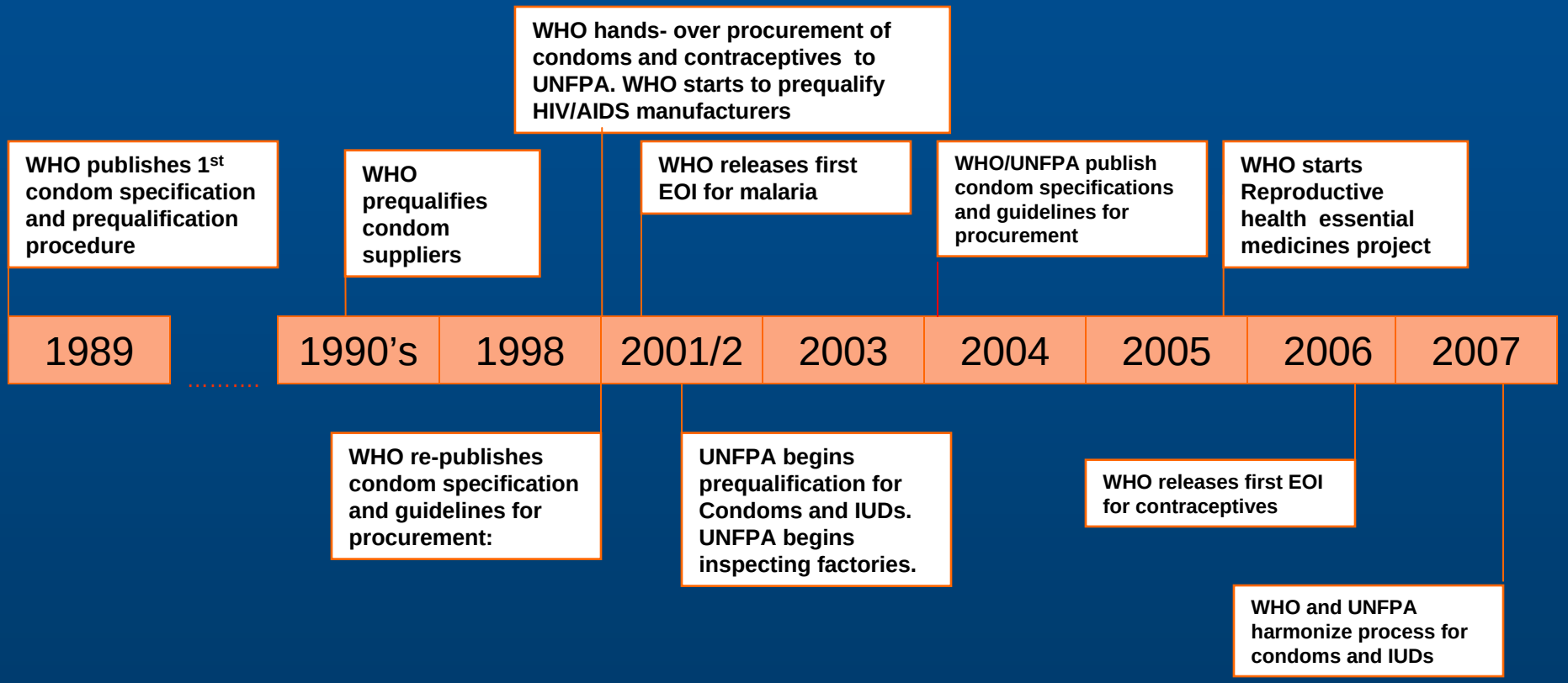
UNFPA

PATH
A catalyst for global health

Session Objectives

- Introduce the key differences between the new and old WHO/UNFPA prequalification scheme
- Understand the required steps in the new scheme
- Discuss common problems encountered during prequalification
- Determine when it makes sense for manufacturers to seek prequalification

Prequalification Programme Timeline



Note the trend toward using prequalification as a system for mitigating product quality risks

Condom Prequalification: New Scheme

- Publication of invitation for expression of interest (EOI) by WHO and UNFPA
- Submission of documents by manufacturer
- Initial screening for completeness of documents
- Assessment of manufacturer submission
- Site inspection
- Sampling and testing
- Report and outcome
- Periodic reevaluation

Key Differences Between New and Old Schemes

- Specific application schedule
- Manufacturers must submit more documentation
- ISO 13485 is a prerequisite
- Inspection will not change significantly, but inspection report will be reviewed before release
- List of prequalified manufacturers will be public

World Health Organization

United Nations Population Fund

Prequalification Scheme

for the Male Latex Condom

PROCEDURE FOR ASSESSING THE ACCEPTABILITY, IN PRINCIPLE, OF MALE LATEX CONDOMS FOR PURCHASE BY UNITED NATIONS AND OTHER AGENCIES

Step 1: Invitation for Expression of Interest (EOI)

- At regular intervals, manufacturers are invited to submit an EOI
- Invitation will be published on UN Global Marketplace, UNFPA, and WHO websites
- Manufacturers given until December 31 to submit EOI

Step 2: Submit EOI to UNFPA

- Manufacturer must submit the following documentation:
  - Letter of application
  - Confirmation of legal status
  - Product dossier
  - Site master file (SMF)
  - Condom samples

Step 3: Initial Screening for Completeness of Documents

- Overall submission:
  - If complete, continue review of documentation
  - If incomplete, manufacturer will be asked to complete the documentation and resubmit within 90 days

Step 4: Assessment of Manufacturer Submission

- Outcomes of documentation assessment:
  - If the manufacturer meets the minimum requirements, a site inspection will be scheduled

Step 5: Site Inspection

Who:

- Performed by experts appointed by UNFPA

When:

- UNFPA decides the dates

What:

- All aspects of the condom production facility subject to inspection
- Includes, but not limited to, Technical Inspection Checklist Guide (Annex 3)

Step 6: Sampling and Testing

- Product samples will be taken
- Sample size in accordance with ISO 4074
- Range of tests conducted in accordance with WHO Specification
- All testing conducted by independent, competent testing laboratories
- Copy of test report provided to manufacturer
- Further sampling could be conducted if deemed necessary by inspector

Step 7: Report and Outcome

- Inspection report provided to manufacturer and UNFPA
- More detailed inspection report with recommendations provided to UNFPA
- UNFPA recommends to manufacturer:
  - Prequalification without conditions
  - Prequalification subject to specified corrective action
  - Corrective action and possible repeat site inspection
  - Site ineligible for prequalification

Resolution of Disputes

- WHO prequalification process allows for manufacturer appeals and complaints

Listing of Prequalified Manufacturers

- Prequalified manufacturers will be listed on WHO and UNFPA prequalification websites
- Prequalification lists will be maintained and updated by UNFPA

Example List of Prequalified Condom Suppliers

STATUS OF CONDOM PRE-QUALIFICATION

Pre-qualified Condom Manufacturers – August 2007

FACTORY	COUNTRY	FACTORY LOACTION
Bangla German	Bangladesh	Savar, Dhaka
Beiersdorf Medical Latex (DUA)	Malaysia	Senai, Johor
Condomi	Germany	Erfurt
CPR	Germany	Sarstedt
Dongkuk Vietnam	Vietnam	Viet Tri City
Dongkuk Techno	Malaysia	Kedah Darul Aman
Dongkuk Trading	Korea	Seoul
Guilin United Med Health	China	Guilin
Hindustan	India	Trivandrum
INAL	Brazil	Sao Roque
Indus Medicare	India	Ramaipally
Qingdao	China	Qingdao
Suretex Ansell	Thailand	Surat Thani
Suretex Prophylactics ltd.	India	Bangalore
Techni Latex	Spain	Madrid
Thai Nippon	Thailand	Thungsukla, Siracha, Chonburi
TTKLIG	India	Virudhunagar
TTKLIG	India	Pallavaram, Chennai
UNIDUS	Korea	Chungbuk

Requalification of Manufacturing Sites

- Requalification undertaken at intervals of no more than three years
- Consists of comprehensive evaluation of documentation, site inspection, and product testing

Requalification of Manufacturing Sites

Can also occur if:

- Condoms supplied by manufacturers are considered to NOT be in compliance with agreed specifications
- UNFPA or other UN agency or organization receives complaint considered serious
- Significant change in any matter affecting the information on which initial approval was based

Workshop Aids

- Manufacturer self-assessment tool
- Individual meetings with WHO/UNFPA technical experts

Small Group Discussion

- What kind of information does the executive management need to know before seeking prequalification?
- What obstacles, if any, do you anticipate in this process?
- What additional information would be helpful for you to take home from this workshop?

Manufacturer Self-Assessment Tool

	Already Have Necessary Documentation or Already Meet Necessary Requirements	Know How to Complete Necessary Documentation or Understand How to Meet Necessary Requirements	Need Further Clarification or Assistance
Site Master File Summary			
1. General Information			
2. Personnel			
3. Premises and Equipment			
4. Documentation			
5. Production			
6. Quality Control			
7. Distribution, Complaints, and Product Recall			
8. Self-Inspection			
Product Dossier Summary			
1. Characteristics of Products			
2. Raw Materials			
3. Sites of Manufacture			
4. Manufacturing Process			
5. Control of the Products			
6. Test Procedures			
7. Shelf Life Data			
Shelf Life			
1. Real Time			
2. Accelerated			

	Already Have Necessary Documentation or Already Meet Necessary Requirements	Know How to Complete Necessary Documentation or Understand How to Meet Necessary Requirements	Need Further Clarification or Assistance
Safety and Biocompatibility			
1. ISO 10993			
• Evaluation and testing			
• In vitro cytotoxicity			
• Irritation and delayed-type hypersensitivity			
2. Nitrosamines			
3. Protein Allergies			
4. Dusting Powders			
5. Smell			
Quality Management			
1. ISO 13485 – Cl 4			
• Is there a QM system?			
• Is it documented?			
• Do you keep records?			
2. ISO 13485 Cl 5			
• Is top management committed?			
3. ISO 13485 Cl 6			
• Are sufficient resources provided?			
4. ISO 13485 Cl 7			
• Is production planned?			
• Is process validated?			
• Is there a risk management plan available?			
• Is the product traceable			

	Already Have Necessary Documentation or Already Meet Necessary Requirements	Know How to Complete Necessary Documentation or Understand How to Meet Necessary Requirements	Need Further Clarification or Assistance
through production?			
• Is there an orderly design process?			
• Is the QC system adequate?			
Statistical Quality Control			
Final product testing – use of ISO 2859-1			
Choice of sampling scheme			
Switching rules			
In-process testing			
1. ISO 3951			
2. Control charts			
Site Inspection			