Procurement Services Branch

Delivering supplies for reproductive health results

The WHO/UNFPA Prequalification Programme and Quality Management in the Procurement of RH commodities

November 2015

Outline of presentation

- Background on UNFPA
- Overview of UNFPA Procurement
- Prequalification Programme
- Tendering with UNFPA
- Quality Standards and Quality Assurance
- Collaborative Activities in the Procurement of Quality Products

Background on UNFPA

UNFPA is the lead UN agency for reproductive and sexual health

UNFPA promotes the right of every woman, man and child to enjoy a life of health and equal opportunity

- Network of offices in **150 countries**
- **Working with** governments and through partnerships with other UN agencies, civil society and the private sector
- Providing **technical expertise**
- Supporting countries in using population data for policies and programmes

UNFPA's target

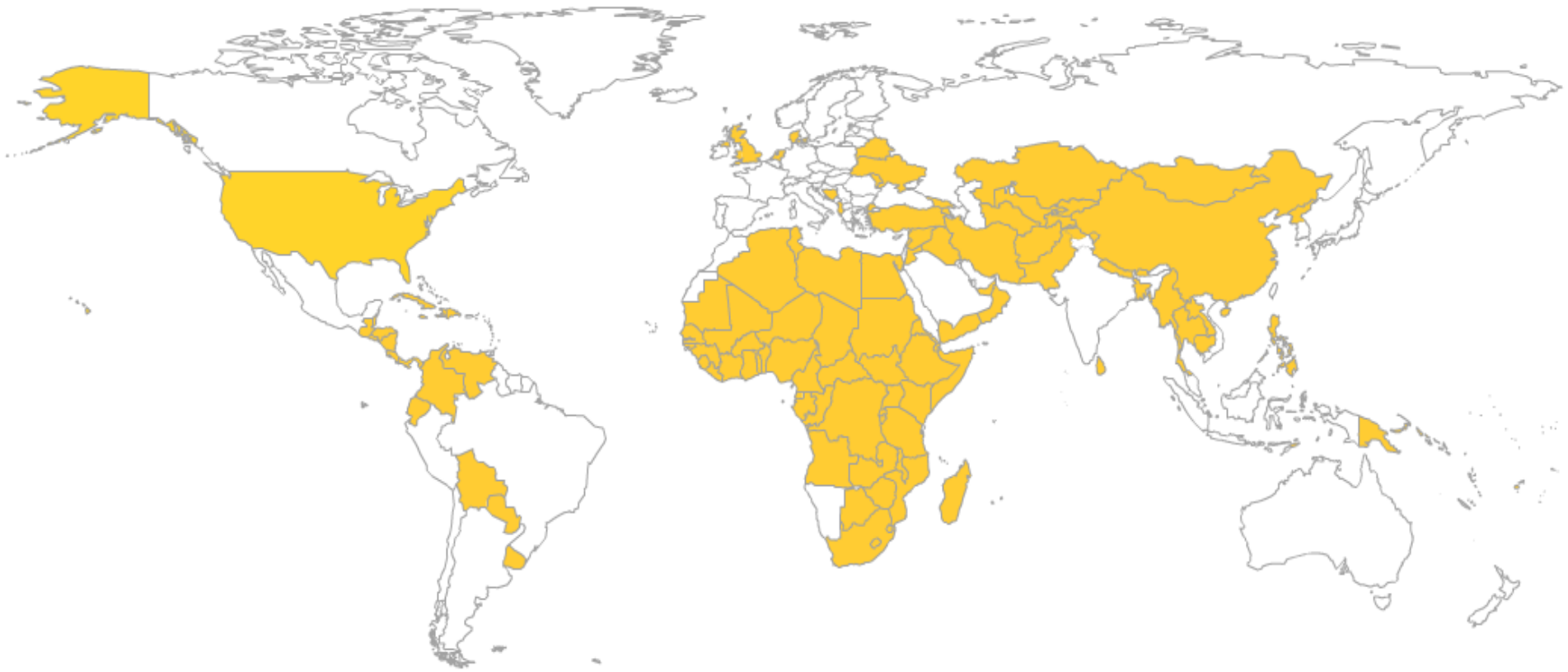
Every **pregnancy** is wanted, every **birth** is safe, every young person is free of **HIV/AIDS**, and every girl and woman is treated with dignity and respect.

Procurement Services Branch (PSB)

Delivering supplies for reproductive health results

- Since over 40 years
- Managing a global supply chain
- Partnering with:
  - Governments
  - Program donors
  - NGOs

PSB Delivered RH Goods to 113 Countries



Provided 39 million couple years of protection (CYP) in 2014

2014

Total PSB procurement 2014
$216M

$132M	Contraceptives
$25M	Medical equipment
$12M	Pharmaceuticals

RH commodities = 78% of total PSB spend in 2014

Overview of UNFPA RH Commodity procurement

Contraceptives

- Oral contraceptives
- Injectables
- Implants
- Male and female condoms
- IUDs

Medical Devices

- Medical Equipment, surgical instruments, medical supplies
- Emergency RH Kits

Essential Sexual and Maternal Health Medicines

- Analgesics
- Oxytocics
- Antibiotics

In 2014, UNFPA delivered about

1,006,000 IUD

Value $326,000

765,000,000 MC

Value $21,323,000

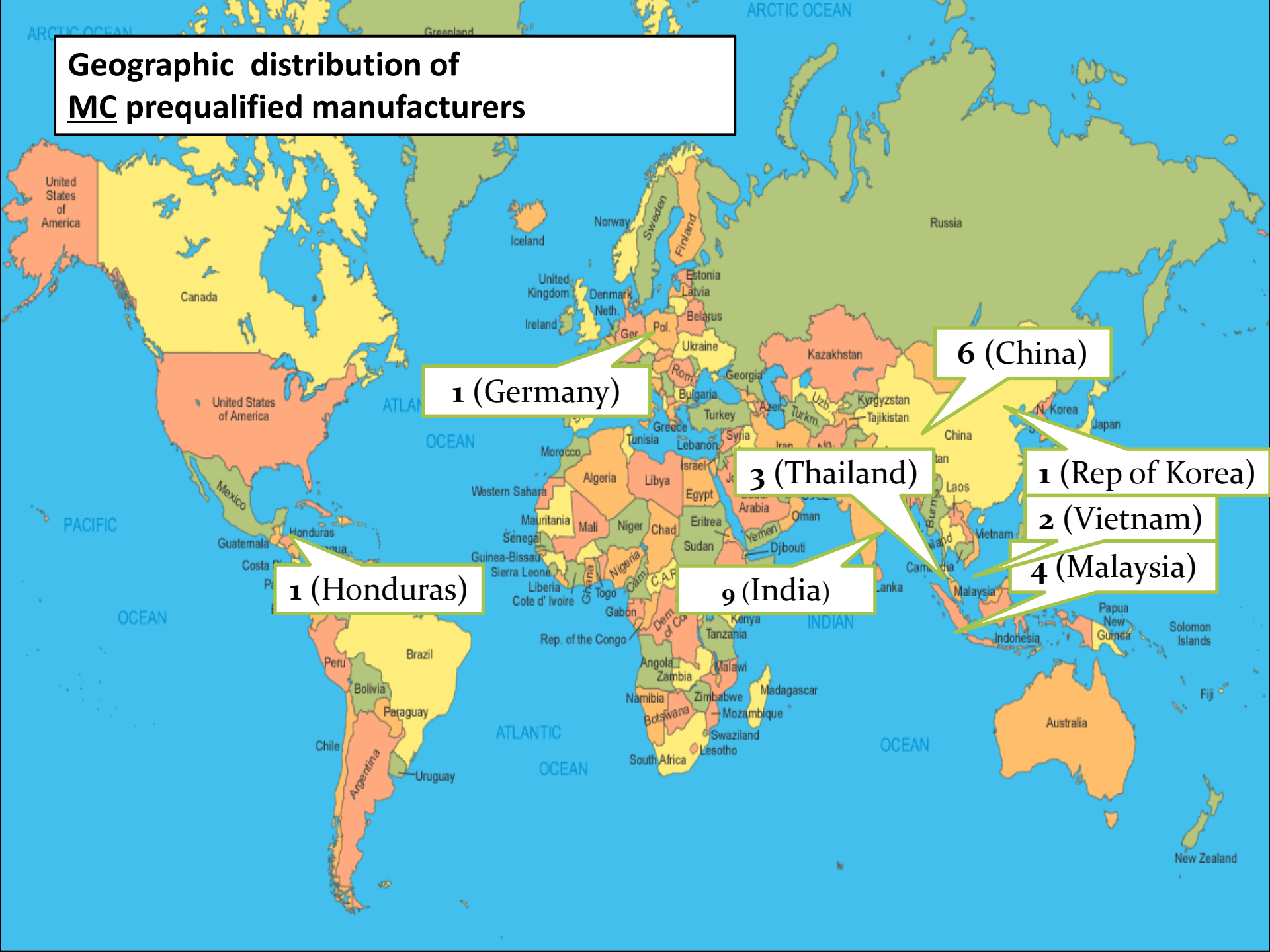
14,800,000 FC

Value $8,200,000

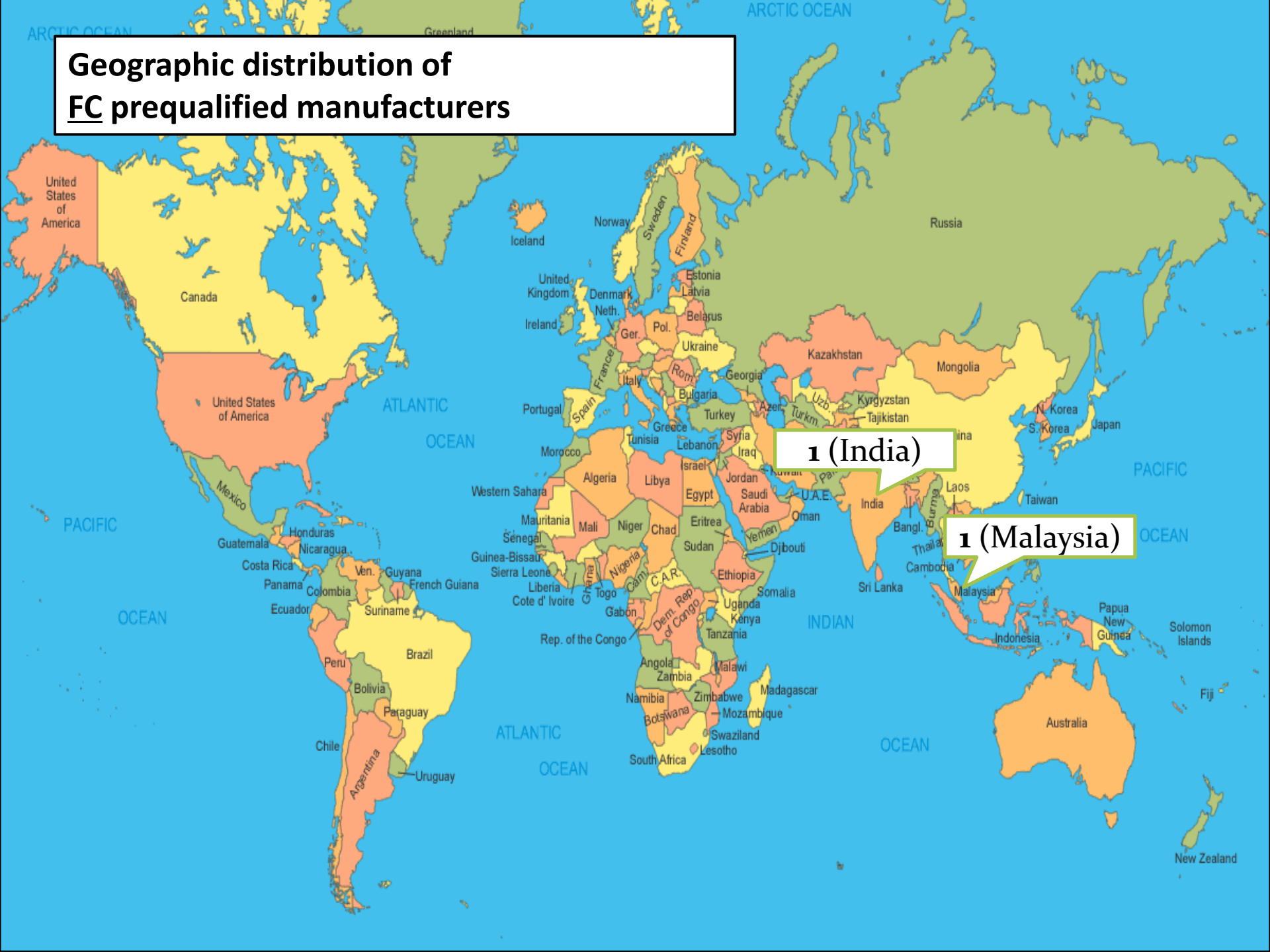
Prequalified Manufacturers

(https://www.myaccessrh.org/prequalification-programme)

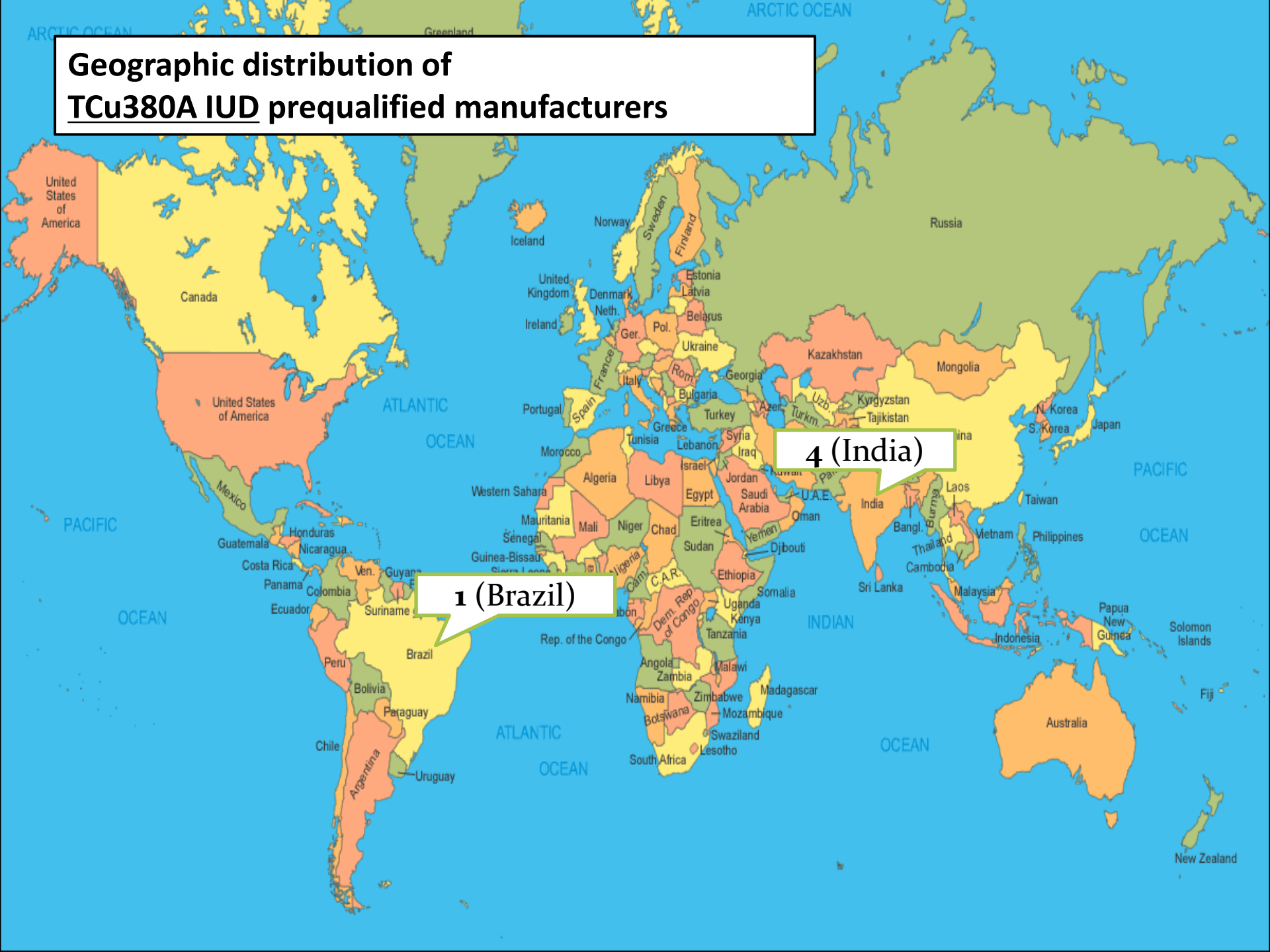
2		UNFPA holds **2** LTAs with manufacturers
27		UNFPA holds **12** LTAs with manufacturers
5		UNFPA holds **3** LTAs with manufacturers


Geographic distribution of
MC prequalified manufacturers
1 (Germany)
6 (China)
3 (Thailand)
1 (Rep of Korea)
2 (Vietnam)
4 (Malaysia)
1 (Honduras)
9 (India)
ARCTIC OCEAN
Greenland
Iceland
Norway
Sweden
Finland
Russia
United States of America
Canada
United Kingdom
Ireland
Denmark
Neth.
Ger
Pol.
Estonia
Latvia
Belarus
Ukraine
Kazakhstan
Georgia
Bulgaria
Turkey
Greece
Tunisia
Syria
Lebanon
Israel
Morocco
Algeria
Libya
Egypt
Western Sahara
Mauritania
Mali
Niger
Chad
Eritrea
Sudan
Arabia
Oman
Yemen
Djibouti
Senegal
Guinea-Bissau
Sierra Leone
Liberia
Cote d' Ivoire
Ghana
Togo
Nigeria
Cam.
C.A.R.
Gabon
Dem. of Co
Rep. of the Congo
Kenya
Tanzania
Angola
Zambia
Malawi
Namibia
Zimbabwe
Mozambique
Madagascar
Botswana
Swaziland
Lesotho
South Africa
Kyrgyzstan
Tajikistan
Uzb.
Turkm.
N. Korea
Japan
China
Laos
Vietnam
Malaysia
Indonesia
Papua New Guinea
Solomon Islands
Fiji
Australia
New Zealand
Sri Lanka
Mexico
Guatemala
Honduras
Costa Rica
Brazil
Peru
Bolivia
Paraguay
Chile
Argentina
Uruguay
PACIFIC
OCEAN
ATLANTIC
OCEAN
INDIAN
OCEAN

Geographic distribution of FC prequalified manufacturers



Geographic distribution of TCu380A IUD prequalified manufacturers



Medical Devices for Reproductive Health:
Progress of applications in the prequalification of male condoms, female condoms and IUD

Requalification process not listed

Date: November 2015

		Manufacturer responded to EoI	Document Review	Site Inspection	Capa	Prequalified
MC	Manufacturing sites	1				
MC	Manufacturing sites		2			
MC	Manufacturing sites			3		
MC	Manufacturing sites				5	
MC	Manufacturing sites					27
FC	Products	2				
FC	Products		3			
FC	Products			1		
FC	Products					
FC	Products					2
TCu380A IUD	Manufacturing sites	1				
TCu380A IUD	Manufacturing sites					
TCu380A IUD	Manufacturing sites					
TCu380A IUD	Manufacturing sites				1	
TCu380A IUD	Manufacturing sites					6

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The WHO/UNFPA Prequalification Programme

UNFPA's Role in the Prequalification Programme:

Prequalification programmes started in 2001 (WHO's normative and standard setting role)

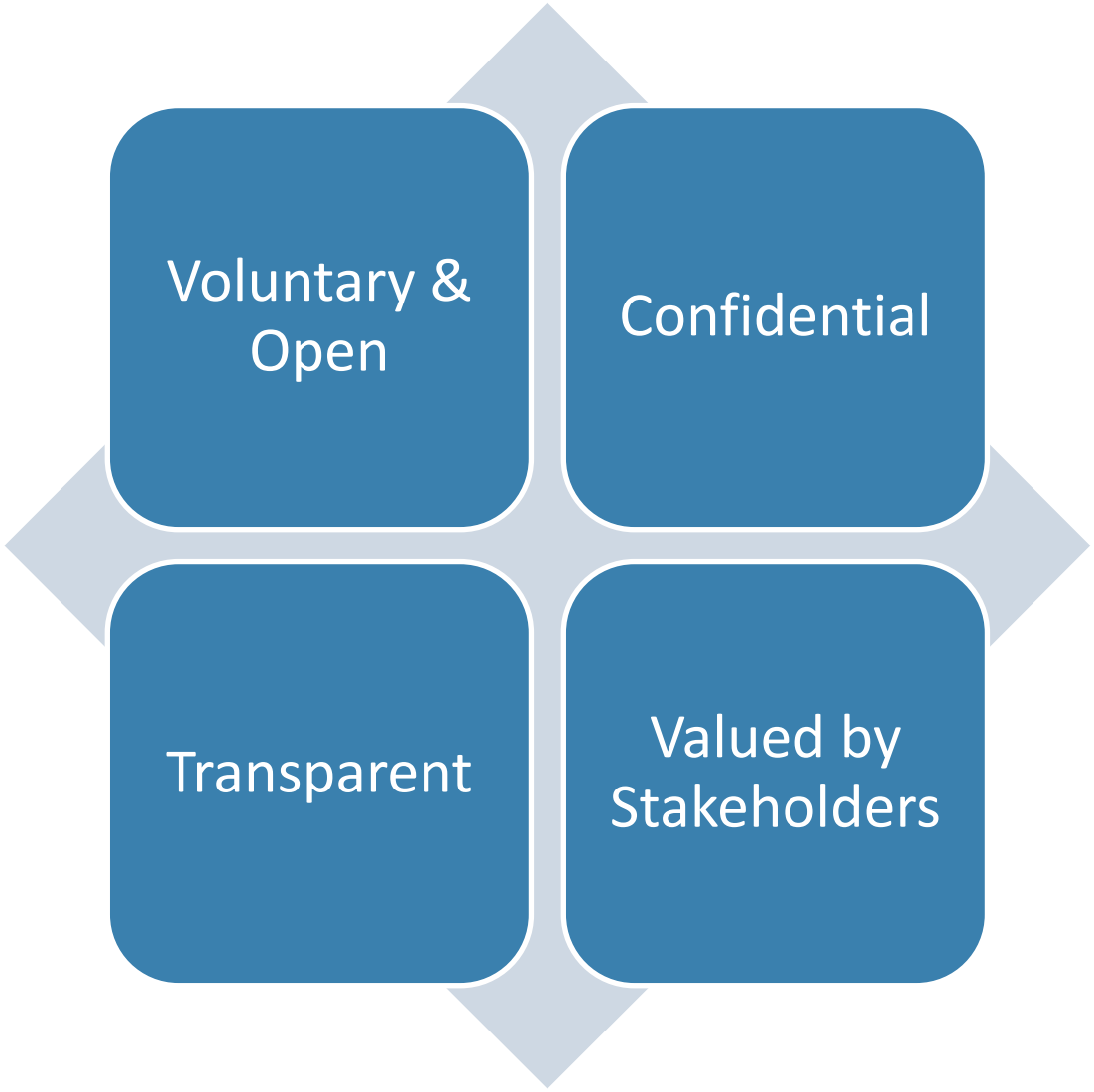
In 2005 WHO delegated UNFPA to manage the prequalification of condoms and intrauterine devices

UNFPA aims to evaluate all suppliers that express interest

Aims of the Prequalification Programme

- Ensure that manufacturers have effective quality management systems in place and meet product quality standards
- Determine the physical capacity of manufacturers to deliver required quantities of products
- 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

Basic Principles of Prequalification



Basic Principles of Prequalification 2

Voluntary

Voluntary scheme open to all willing manufacturers since 2001 to assess the quality and safety of products.

Open

Currently no charge to manufacturer as UNFPA bears all the costs to the document review by experts, inspection costs. UNFPA appreciates assistance with daily transport to/from hotel to factory.

Basic Principles of Prequalification 3

Confidential

All **documents** submitted, information, details of the inspection are confidential to UNFPA.

All UNFPA **inspectors** are bound by UNFPA confidentiality rules and therefore cooperation and openness to questions by the inspection team are critical to whole process.

Inspection reports are not shared publicly and remain confidential to UNFPA and the manufacturer.

Requesting permission for taking **photographs** – the pictures taken only purpose are for supporting the report and for UNFPA's files; they will not be shared with external parties.

Basic Principles of Prequalification 4

Valued by Stakeholders/Legitimacy

Approved by the WHO Expert Committee system – WHO Member States & WHO governing bodies

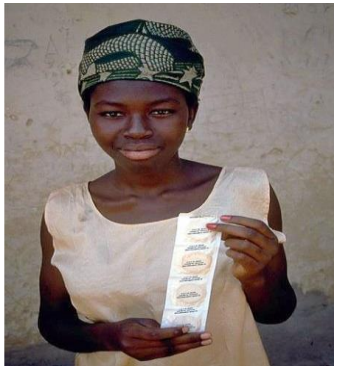
Supported by the International Conference of Drug Regulatory Authorities

Transparency

Information on prequalification process is available on the WHO and UNFPA prequalification websites:
http://www.unfpa.org/resources/male-latex-condom
http://www.unfpa.org/resources/female-condom
http://www.unfpa.org/resources/tcu380a-intrauterine-contraceptive-device-iud-specification-prequalification-and

Objectives of Prequalification

- Ensure high quality commodities
- Access low cost devices that meet international standards and quality requirements in line with WHO specifications and guidelines
- Harmonize quality standards through pooled procurement
- Ensure safety and efficacy throughout shelf life



WHO/UNFPA Prequalification Process

1. Publication of the EOI – Manufacturers respond and submit the required documentation
2. Initial screening for completeness of documents
3. Detailed and technical assessment of manufacturer's document submission - Technical Review Committee for FC
4. Site/factory inspection incl. product sampling and testing
5. Factory Inspection Report and Corrective/Preventative Action reports
6. Prequalification
7. Maintenance & on-going compliance testing, re-qualification every 3 years

Female Condoms varieties =

Technical Review Committee for FC

The UNFPA condom tender process

After Product and Manufacturing Site are prequalified, suppliers can participate in tender activities with UNFPA with the target to get into Long Term Agreements (LTA)

Suppliers shall:

- Obtain Pre-Qualified Status
- Check UNGM for tenders of interest
- (All preq. manufacturers will be invited by PSB)
- Participate in tenders
- If awarded a long-term agreement/contract, maintain high quality of product

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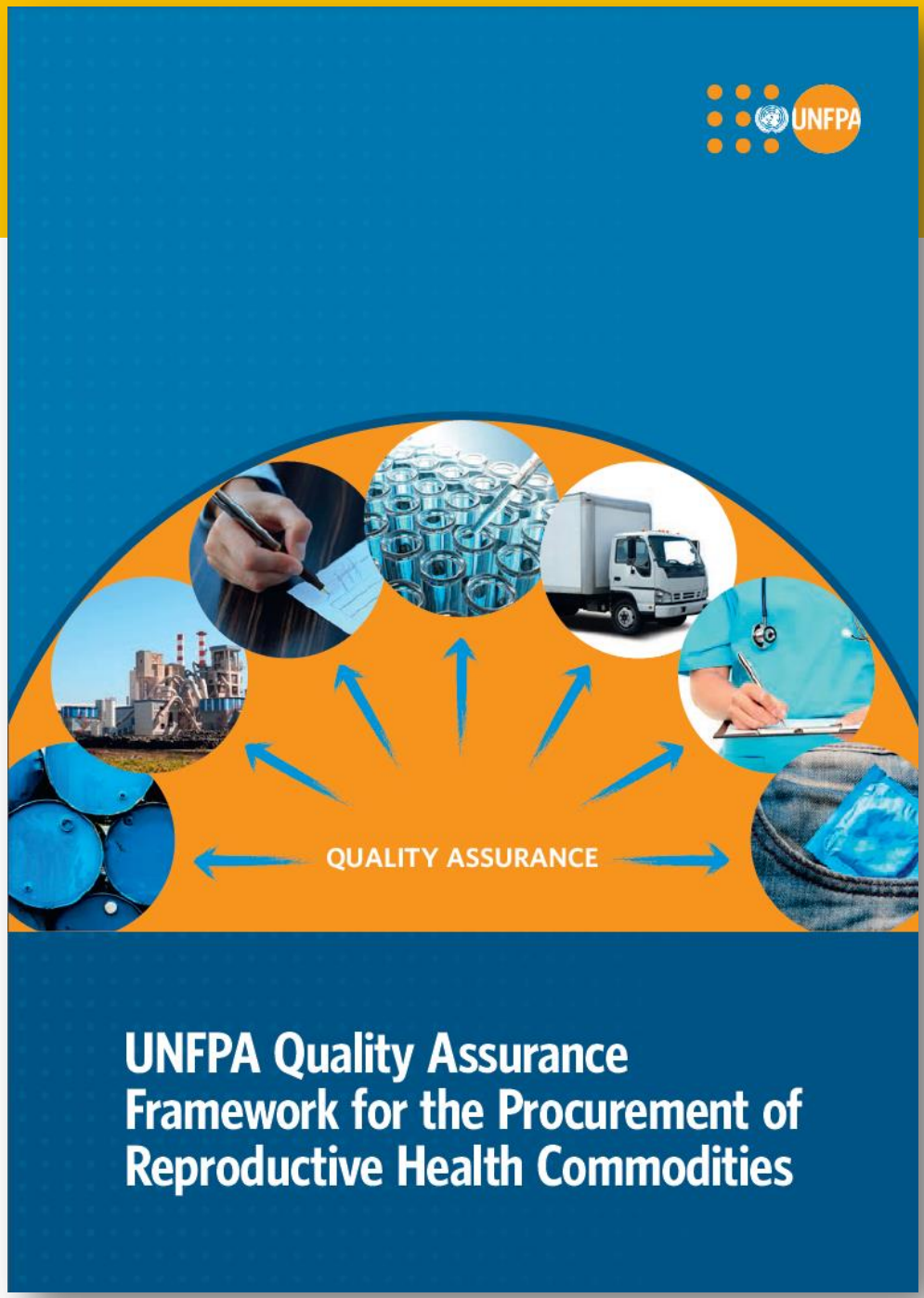
Quality Management

UNFPA Quality Assurance Framework for the Procurement of RH Commodities

Published in 2014

Compiled by the QA team in UNFPA PSB

http://www.unfpa.org/resources/unfpa-quality-assurance-framework



UNFPA QA Criteria & Technical Specifications

Male/female condoms & TCu380A IUDs

- Must be WHO/UNFPA prequalified
- Must adhere to requirements of relevant WHO/UNFPA specifications (based on ISO standards)

Medical devices

- Technical evaluation during bidding process
- ISO 13485 QMS, proof of product approval (CE or equivalent)

Hormonal contraceptives and RH medicines under WHO Prequ. Programme

- WHO Prequalified
- Approval by a Stringent Regulatory Agency* (SRA)
- Recommendation by WHO Expert Review Panel (ERP)

All other pharmaceuticals not under WHO Prequalification Programme

- Internal Prequalification System -based on Model Quality Assurance Systems (MQAS) of Procurement Agencies – WHO guideline

QA in the Prequalification & Procurement Process

- Rigorous, well established process
- Factory inspection
- Product testing by ISO 17025 accr. Quality Control Laboratories(QCL)
- Continuous quality monitoring

Prequalification

Pre-shipment testing

- All UNFPA batches tested by independent QCL (ISO 17025)
- Only batches that pass are shipped to countries (test report)
- Manufacturer also does own quality control testing (Certificate of Analysis)

- Quarterly analysis of all pre-shipment test results for all batches

Continuous quality monitoring

- Early flags / notifications for manufacturer performance
- Re-qualification inspections every 3 years

MC/FC Pre-Shipment Inspection, Sampling and Testing

- Inspection
  - Packaging, markings and labeling as per buyer's request
- Sampling
  - Sampling agency draws samples in accordance with ISO 2859-1
- Testing
  - ISO 17025 accredited laboratory tests condoms for all performance and quality parameters in accordance with specification, ISO 4074 & PO requirements
- Inspection & Testing Reports
  - Must be sent to consignee

UNFPAs position on Post-shipment Testing

Post shipment testing aims to prevent **products, that do not meet quality standards**, from entering the distribution system.

In some cases failures do not directly link to the quality of the manufacturing process due to confounding factors, e.g. limited local testing capacity: equipment, technical skill, resources, volumes, etc.

UNFPA RECOMMENDATION

- *Do risk based approach on the decision of post shipment testing (cause related) as opposed to mandatory post shipment testing*
- *Do post market surveillance*

If post-shipment testing is necessary, it should by performed by an ISO 17025 accredited laboratory, having male condom testing within the scope of its accreditation

Testing must use specification/standard that the products were produced against

Results of the Temperature Monitoring Study

- Shipments to Africa and LAC region
- 3 Temperature data loggers placed (~ 50 shipments) pre-shipment inspection and sampling for testing
- Tracking starts from manufacturer's warehouse – transport to vessel - on the vessel – on port of arrival – local warehouse when released for distribution
- Data showed no temperature hikes during transit
- Some shipment had temperature hikes at the port. One shipment had a hike at manuf. warehouse – worked on approving conditions in warehouse

➢ *Improve conditions at receiving port*

➢ *Critical: Clearing process to be short to limit exposure time*

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Collaborative Activities in the Procurement of Quality Products

- **Workshops with manufacturers** to cover specifications and PQ processes (e.g. 2011 FC Thailand, 2014 FC&MC in Malaysia)
- **Workshops with Quality Control Laboratories** (QCL) to harmonize testing standards, improve capacity, support preparation for ISO 17025 accreditation (e.g. Ghana, Tanzania, Mexico, Kenya, Botswana, Ethiopia)
- **Dossier Assessment Workshop** with MoH, NRA, Laboratories (e.g. 2015 Southern Africa Region)
- **Inclusion of NRAs** (of recipient countries) in document reviews and factory inspections to increase recognition and support of the PQ programme
- **Consensus required between procurement agencies, NGOs and NRAs: harmonisation of procurement practices**

Procurement Services Branch

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