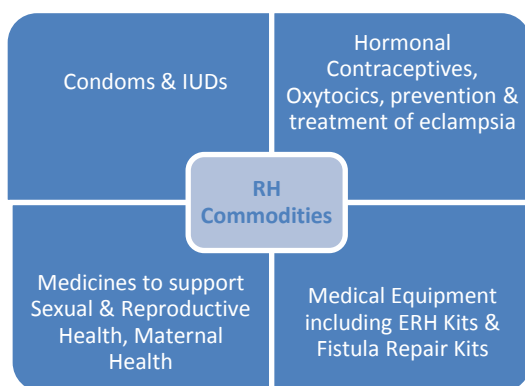


QUALITY ASSURANCE – Whose responsibility is it?

For a QA system that yields results and success, the **key input is team work**. Your feedback and comments are very helpful for improving the quality of commodities and the QA system, please alert the QA team with any quality and technical related issues as they occur so we can help to solve and keep track for future related issues and better performance from suppliers.

Quality Assurance of Reproductive Health Commodities

UNFPA is the lead UN agency in the procurement of reproductive health commodities. To support national and global efforts to increase access and availability of reproductive health commodities, the Procurement Service Branch (PSB) has to ensure that commodities supplied meet international quality standards at all



times. Based on evaluation of products and equipment previously delivered, PSB in the last few years has worked at strengthening Quality Assurance procedures and implementing activities that ensure commodities of acceptable unified quality standards.

In these efforts, PSB has promoted collaboration with major partners and stakeholders who play a key role in the quality of commodities that UNFPA procures. WHO, UNICEF, Global Fund, FHI, are some of our collaborators. Assessment and selection is not only based on the lowest price as everything

now follows a structured quality assessment system:

The components of the strengthened QA system have the following activities:

1. Prequalification

- i. Based on submitted documentation and data, the review & evaluation of quality, safety and efficacy
- ii. On-site factory inspections by qualified and experienced experts

2. Review by panels made up of Technical Independent Experts

- i. Review & updating of technical specifications
- ii. Review & Evaluation of technical requirements for each commodity

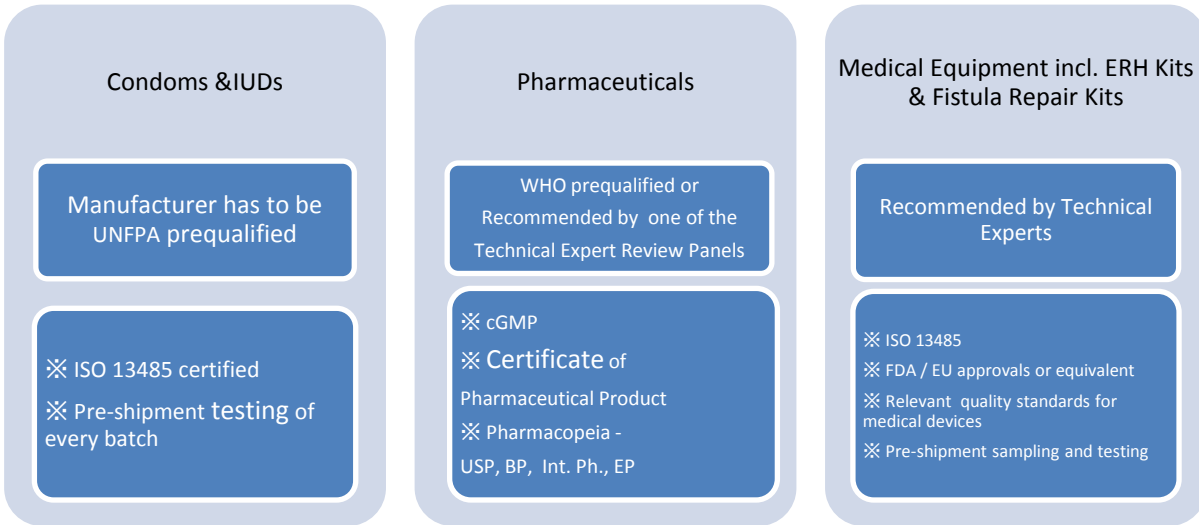
3. Inspections of manufacturers and warehouses

- i. Factory Inspections according to international standards
- ii. Sampling and Testing of commodities
- iii. Review of Prequalification or Re-evaluation of suppliers.

Fundamental factors to be assessed

- Raw materials suppliers
- Manufacturers
- National Regulatory Authority
- Quality Control Laboratories
- Procurement unit
- Logistics system
- End user

The selection of suppliers and product is based on:

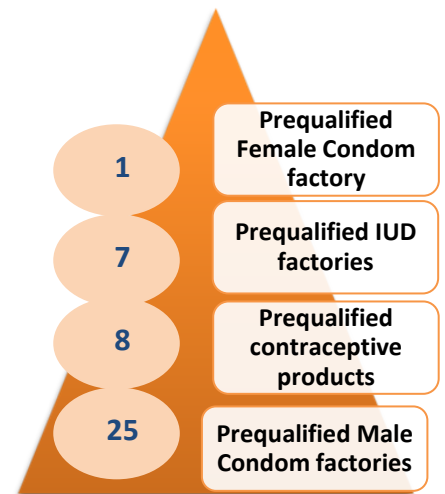


Current status of RH Commodities as of 31 January 2011

PSB has been ensuring reproductive health commodity security by the prequalification process for manufacturers of **IUDs and condoms** since 2001. The prequalification process is in line with the **World Health Organization (WHO) Prequalification standards**. As a result, UNFPA, WHO, UNAIDS and other UN Agencies only procure condoms from suppliers that have been qualified according to this QA process. Once the factory sites have been prequalified they are subjected to **continuous quality control**. Therefore, **pre-shipment sampling and testing** for condoms is a requirement for each and every batch.

Pharmaceuticals depending on their category have to be WHO prequalified or recommended for procurement by one of the Technical Review panels as well as satisfy the technical requirements above. Medical equipment undergoes pre-shipment inspection, as well as random sampling and testing.

For any quality and technical related matters for condoms, IUDs, pharmaceuticals and medical equipment, please email directly to: Agnes Chidanyika – chidanyika@unfpa.org; Isabel Lucas Manzano – manzano@unfpa.org; Roberto Mena – mena@unfpa.org and copy Morten Sorensen (Deputy Chief of PSB) – sorensen@unfpa.org and Eric Dupont (Chief of PSB) – dupont@unfpa.org.



“Quality is not an act, it is a habit”

Aristotle

(Ancient Greek Philosopher, Scientist and Physician, 384 BC–322 BC)