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:

- **Condoms & IUDs**
  - Manufacturer has to be UNFPA prequalified
  - ※ ISO 13485 certified
  - ※ Pre-shipment testing of every batch

- **Pharmaceuticals**
  - WHO prequalified or Recommended by one of the Technical Expert Review Panels
  - ※ cGMP
  - ※ Certificate of Pharmaceutical Product

- **Medical Equipment incl. ERH Kits & Fistula Repair Kits**
  - Recommended by Technical Experts
  - ※ ISO 13485
  - ※ FDA / EU approvals or equivalent
  - ※ Relevant quality standards for medical devices
  - ※ Pre-shipment sampling and testing

**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)