UNFPA QA Requirements for Procurement of Non-LTA RH medical products

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This document is a subsidiary of the UNFPA Procurement Procedures.

I. General principles of quality assurance of pharmaceuticals, IVDs and medical devices

It is imperative that all health products: pharmaceuticals, In-vitro Diagnostics (IVDs) and medical devices meet internationally accepted safety standards. These standards are set out by WHO Essential Medicines and Health Products Department whose requirements are in alignment with the requirements of other large regulatory bodies such as the European Commission and U.S. Food and Drug Administration (FDA). For example, UNFPA Quality Policy on reproductive health (RH) medicines stipulates the standards that procured medicines are expected to meet. This ensures that the medicines are of good quality, safe and are efficacious. Supplying medicines, IVDs and medical devices that do not meet the internationally accepted standards is highly risky not only for the people who are being subjected to the possibly lower quality RH commodities in the emergency setting but also for UNFPA as an organization because of the possible negative impact on the organization's image and reputation due to poor quality goods being procured.

II. QA of Non-LTA products

The UNFPA catalog consists of sexual and reproductive health medicines, IVDs and medical devices that are defined in the WHO Essential List of Medicines, WHO Essential list of Medical devices for Maternal and Child Health and WHO Essential list of IDS. These lists are generic and may not include variations that health professionals in all countries use. It is acknowledged that the catalog contains health products that may not meet the needs of all countries, however, it does meet the needs of most countries. All products in the UNFPA have undergone full technical evaluation (product safety, efficacy/performance and quality) to assess compliance with internationally acceptable

quality standards. It follows that all Non-LTA products will have to undergo the same evaluation. All products procured by UNFPA or donated to UNFPA are expected to meet the same internationally acceptable quality standards. Request for Non-LTA products often reach PSB at various times throughout the year and the products are often required for urgent programmatic interventions. This gives PSB very little time to develop generic specifications, solicit bids and perform technical evaluation. Due to the limited time, the full technical evaluation for products marketed in the non-SRA market will not be efficient as it requires a lot of resources and time. To ensure efficiency of delivery of services, PSB developed this guide to assist both PSB and COs when procuring Non-LTA products.

The QA team has established a roster of consultants who may be engaged by COs to develop and perform technical evaluation.

III. Specific QA requirements for Non-LTA products

Technical requirement of Non-LTA SRH products are similar to the LTA product, the only difference is the amount documentation to be submitted by the bidder as well the criteria for acceptance. Products will have to be registered and marketed in SRA countries for pharmaceuticals and for medical devices and IVDs products will be marketed and registered in GHTF founder member NRAs. Guidelines describing the minimum documentation required from the bidders can be found in the tables below as per each product group: Pharmaceuticals, IVDs and medical devices. All certificates and approvals must be valid at the time of bid submission.

QA Non-LTA Guidelines: Pharmaceuticals

1	SRA Questionnaire for Pharmaceuticals completed by bidder.
2	Evidence that the product is registered in the country of intended use.
3	GMP certificate for Finished Pharmaceutical Product (FPP) manufacturer
4	Certificate of analysis for at least one recently released batch.
5	Package insert if applicable and patient information leaflet (PIL).
6	Photos of the finished pharmaceutical product and labeling.

QA Non-LTA Guidelines: *In vitro* Diagnostic (IVD) products

1	Non-LTA Procurement Questionnaire for IVD products completed by bidder.
2	Evidence that the product is registered in the GHFT country of intended use.
3	Minimum documentation: 1. Copy of EC certificate 98/79/EC, and/or 510k/PMA clearance (FDA), and/or other Global Harmonization Task Force (GHFT) Competent Authority certificate or approval letter. 2. WHO Prequalification letter
4	Certificate of analysis for at least one recently released batch.
5	Proof of WHO prequalification *(If not prequalified, see list of other options below)*
6	Photos of the finished IVD product and labeling.

If the IVD product is not WHO prequalified or mentioned on WHO webpage as such, the product* must have undergone:
1) a WHO Emergency Use Evaluation and Listing of IVDs (EUAL), or
2) an US FDA Emergency Use of Medical Products and Related Authorities (EUA), or
3) an approval process from Stringent Regulatory Authority (SRA) designated by Global Harmonization Task Force (GHFT) Competent Authority.
* Any product registered for "Research Use Only" or "For Export Only" is not acceptable, unless specifically authorised in writing by UNFPA.

QA Non-LTA Guidelines: Medical devices and equipment

incl. Personal Protective Equipment (PPE)

1	Non-LTA Questionnaire for Medical Devices completed by bidder/supplier.
2	Minimum documentation as per below table corresponding to classification of Medical Devices (ref. European Commission, MEDDEV 93/42/EEC).
3	Photos of the medical device product and packaging (*preferably in a format where the dimensions and features can be visually verified*).

Product class (as per EC MEDDEV)	Minimum documentation required for Medical Devices
class I (non-measuring, non-sterile and/or non-reusable surgical instrument, rsi)	1. Copy of ISO 13485 or ISO 9001 QMS certificate. 2. A signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the relevant ISO standards and directives (e.g. CE self-declaration 93/42/EEC), and which has a reference to the offered product.
class I measuring **class I sterile** **class I rsi** **class IIa**	1. EC certificate (referencing the name/number of the notifying body), and/or 510k (FDA clearance), and/or approval letter or certificate from national regulatory body. 2. A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. for sterilization, ISO 13485 QMS) and directives, and which has a reference to the offered product. **Note***:* If a sterilization activity is subcontracted to a third party, ISO 13485 QMS compliance is also required from the subcontracting company.
class IIb **class III**	1. EC certificate (referencing the name/number of the notifying body) with an additional copy of EC Design Examination certificate, and/or 510k/PMA FDA clearance, and/or approval letter or certificate from national regulatory body. 2. A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. ISO 13485 QMS) and directives, and which has a reference to the offered product. Proof of compliance to ISO standards in a form of copies of certificates shall be submitted if available.

Examples of products in each of the Medical Device EC MEDDEV class:

Class I (non-measuring, non-sterile and/or non-reusable surgical instrument)

Aprons, bags, baskets, bowls, etc. (largest item class group in UNFPA procurement catalog).

Class I (measuring, sterile and/or reusable surgical instrument)

Thermometers, scales, catheters, cytobrushes, sterile surgical and gynecological instruments, sterile gloves and supplies, reusable surgical and gynecological instruments, etc.

Class IIa

Cannulas, needles, blades, pumps (manual, electrical), resuscitators, etc. (Many of the class IIa products are also sterile products.)

Class IIb and III

Anaesthesia machines, cryosurgical units, sutures, baby warmers and incubators, infusion pumps etc.