UNFPA PRODUCT QUALITY ASSURANCE

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Outline

Medicines

- Product Quality Assurance
- Core Medicines
- Technical evaluation
- Typical issues/deficiencies observed during technical evaluation
- Other planned activities
- Local procurement

Medical devices

- Common issues:
  MDs
  Contraceptive Devices
  IVDs
- Challenges
- The way forward

Product Quality Assurance

Upholds and **integrates all aspects of international quality management systems** throughout the supply chain of sexual and reproductive health products.

Technical Services

Develops technical specifications and conducts technical evaluations of SRH products, medicines and devices.

Quality control & monitoring

Performs quality control and monitors quality compliance through to the last mile.

Pre-qualification programme

Evaluates suppliers to ensure they meet WHO international quality standards

Core Medicines

- Interagency list of essential medicines for reproductive health - contraceptives and medicines for maternal health
- UNFPA procures only RH medicines, which are invited for WHO PQ programme i.e those that meet the following quality standards:

➢ Prequalified by the WHO PQ

➢ Authorized for use by an SRA/WLA

➢ Recommended for use by an Expert Review Panel (ERP)

Non-Core Medicines

Authorized for use by an SRA/WLA

Approved by other (including country of origin) and meeting the following requirements:

- WHO TRS
- ICH
- Any other relevant international guidelines

Typical issues observed during technical evaluation

Hormonal contraceptives with a device component	Hormonal contraceptive pills	Priority maternal health pharmaceuticals	Other essential Pharmaceuticals
• Trilingual Artworks lacking • Zone IVb storage conditions for SRA approved products not available • Device component not WHO PQd: o Invalid conformity certification o Insufficient documentation submitted o Products not meeting WHO-PQ or SRA/WLA criteria	• Trilingual Artworks lacking • Zone IVb storage conditions for SRA approved products not available o Products not meeting WHO-PQ or SRA/WLA criteria	• Trilingual Artworks lacking • Zone IVb storage conditions for SRA approved products not available o Products not meeting WHO-PQ or SRA/WLA criteria	• Reluctance to share critical documents when working through 3rd party applicants • Many offers not inclduing all the required documentation • BE studies not submitted • Validation of sterilization processes for sterile products • Product not stable in Zone IV climatic conditions • Trilingual Artworks lacking • Invalid certification • GMP certification from entities which are not recognised by UNFPA

Effect of the deficiencies observed

- Prolonged technical evaluation timelines
- Rejection of submissions
- Less products listed in the catalogue
- Increased risk of safety and efficacy issues

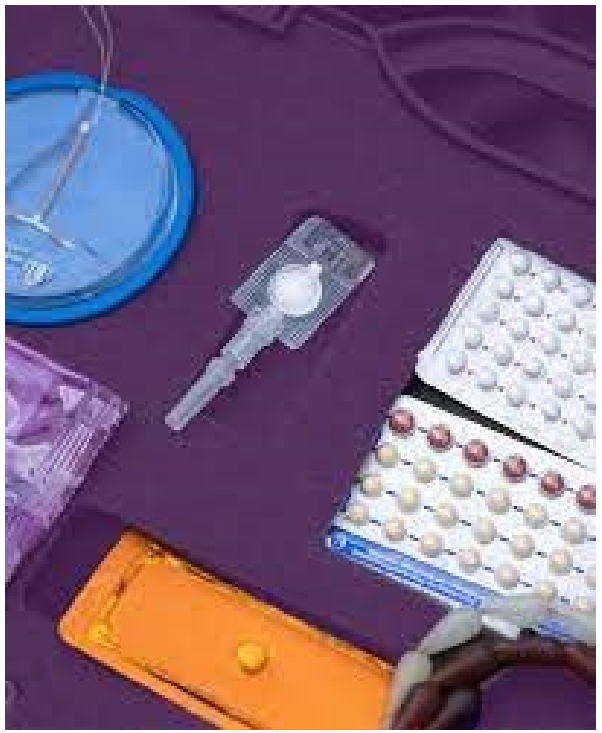
Other planned activities

- Revision of processes to simplify local procurement activities
- Strengthen NRAs for regulation and supply chain management of RH products.
- Market assessments and technical assistance to facilitate regional/local procurement
- Increase the number of suppliers and choices of RH products for supplies
  - *Currently catalogue has less suppliers than desired*
  - *Need to increase these for better supply*

Local procurement

- Reduction in lead times
- A sustainable alternative to regular procurement
    - Promote local capacity and self sufficiency
- Quicker supply in humanitarian situations
- Cost reduction in some instances

Local procurement – Potential pitfalls



- Limited capacity of local suppliers
- Concerns regarding quality of products i.e. meeting the required international standard
- Lack of familiarity with UNFPA requirements
- Limited availability of local suppliers
- Limited range of products from local suppliers

Common issues: Bid submissions and technical dossiers / Medical Devices, IVDs

1. Incomplete information on the technical dossiers

1. Copy and paste

1. Costume made catalogs and brochures

1. IFU only in English

1. Lack on information on the technical specifications offered by the bidders

6. Packaging and labeling missing details

7. Submissions unlabeled, unorganized and without index to follow

8. Answers to clarifications not duly completed as requested or submitted after the deadline

9. Misclassification of the devices

10. Language of the technical dossiers (brochures and catalogues)




11. Partial submission of questionnaires or absence of them

12. Lack of detailed technical specifications to duly perform a technical evaluation

13. Inability to validate certificates (QR code)

14. Post Market Surveillance evidence and reports appropriate for the device Class in accordance with EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR) not submitted




15. Miscellaneous: lack of information on storage, transportation, decommissioning or safe disposal of, sterilization certificates, third-party test reports, warranty, shelf-life, weight, manuals.

16. Bidders not being compliant with sustainability practices requested: ISO 14001.




Common issues: Bid submissions and technical dossiers / Contraceptive Devices

1. Duplication of files

1. Unreadable files

1. Annexes submitted only in pdf format

1. Submissions unlabeled, mislabeled, unorganized or without an index to follow

5. Missing certification of compliance to the product standard (ISO 4074)

6. Poor submission of regulatory approvals in the countries where the product is marketed

7. Distorsion on the address stated in the WHO-UNFPA PQ'd List of Manufacturers and the address declared in the submissions or certificates.

8. Single file submission for more than one manufacturing site-traceability of documents for each site is challenging.




Challenges and lessons learned / Dossier evaluation for medical devices, IVDs / contraceptive devices

1. Transition to MDR, IVDR
2. UDI-DI compliance
3. IVDs Test not WHO PQ'd

6. Systematization and standardization towards a smooth process from the moment of when submitting and offer until final outcomes.




The way forward

1. Improve, update, and systematize the TE templates

1. Update TS, requirements and prices based on market assessments to be performed

1. Expand the suppliers database along the different geographical regions

1. Incorporate new products in the UNFPA catalog

1. Expand the UNFPA portfolio including innovative products




6. Risk-based approach

7. Incorporate suppliers past-experiences into TE templates

8. Market assessment activities, strengthen NRAs

9. Working to ensure sustainable, equitable and timely access to innovative and quality-assured SRH products

10. Streamline change from procurement Agency to SCMU