



LOT 1: RH medicines and other pharmaceuticals - dossier assessment

1. QA Policy for Reproductive Health Medicines

Following international quality standards and supported by WHO and other organizations UNFPA updated implemented in November n April 20121 its Quality Assurance Policy for Reproductive Health Medicines, where highest importance is given to the WHO Prequalification process and the interim ERP process. This latter one aims to prevent interrupted supply of the medicines that are under the WHO Prequalification Programme in the event of less than three prequalified products. This interim process is used as an alternative for quality assessment for those manufacturers that are participating or, are intending to participate in prequalification, but have not yet achieved prequalified status.

2. Background

Additionally to using the WHO prequalification process and the ERP for reproductive health medicines, UNFPA has put in place an Internal Technical Assessment which is based on the Model Quality Assurance System (MQAS) for Procurement Agencies. This process is only used for medicines not included in the Expression of Interest (EOI) under the WHO Prequalification of Medicines Programme. In those cases, UNFPA will assess the submissions taking a risk-based assessment approach and make a decision on procurement of the medicine. The assessment covers the following characteristics product specific: GMP compliance; quality assurance of Active Pharmaceutical Ingredient(s) (API) and the Finished Pharmaceutical Product (FPP) (reference to the latest edition of British, United States, European or International Pharmacopoeias), manufacturing process, validation, stability data and safety and efficacy/therapeutic equivalence.

Following the UNFPA QA Policy for Reproductive Health Medicines the supplier will be responsible for assessing technical submissions of FPP. The submissions will be in the form of the Interagency Finished Pharmaceutical Product Questionnaire (IFPPQ), based on the MQAS and the evaluation will be conducted according to internationally recognized technical standards.

3. Expected Services and Deliverables

a. Assessment of Interagency Finished Pharmaceutical Product Questionnaire (IFPPQ)

The supplier will be asked to review and assess information as submitted in the IFPPQ together with all the annexes. These documents are then checked for authenticity and validity and to determine whether suppliers comply with the internationally recognized standards for quality, safety and efficacy of the submitted finished pharmaceutical product.

Assessment will be conducted based on internationally recognized standards, and specifically following WHO Guidelines, please find some of the main ones below:

- [WHO TRS 929 Annex 4, WHO guidelines for Sampling of Pharmaceutical products and related materials](#)
- [WHO TRS 957 Annex 5, WHO Good Distribution Practices for Pharmaceutical Products](#)
- [WHO TRS 961 Annex 9, Model Guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products](#)
- [WHO TRS 937 Annex 6 Model Quality Assurance System for Procurement Agencies](#)

b. Provision of consolidated results in a template

The supplier will be requested to provide an assessment report per pharmaceutical product evaluated. An assessment template will be provided, where the supplier will be able to elaborate on his/her evaluation. Additionally, the supplier will be able to request extra documentation in case it is considered that it might influence the final result. The feedback provided will help the manufacturer improve towards future assessment in case the result of the current one is not considered satisfactory.

To see the template to be used for the dossier assessment, refer to the Interagency Finished Pharmaceutical Product Questionnaire template attached under the tender notice. It is provided for reference purposes. UNFPA reserves the right to modify the templates during the course of the LTA.

4. Required qualifications and experience

Bidders are asked to propose consultants with the following minimum qualifications:

- Undergraduate degree in pharmacy, chemistry, biochemistry or science.
- Graduate degree in pharmacy, chemistry, biochemistry, or related health field.
- Pharmaceutical background with a minimum 5 years of current work experience in **at least one** of the following technical areas:
 - Quality assurance of pharmaceuticals
 - Quality control of pharmaceuticals
 - Pharmaceutical regulatory affairs
 - Pharmaceutical manufacturing
 - Clinical and/or biopharmaceutics/pharmacokinetics
 - Additional points will be given for three or more years of experience within a National Medicines Regulatory Authority (NMRA), an international pharmacopeia, a UN agency, or an International Organization.
- For each of the proposed consultants, at least 3 completed projects of similar nature and scope in various countries
- For each of the proposed consultants, fluency in English demonstrated through work experience, educational experience, or educational certificates.
- For each of the proposed consultants, willingness to comply with UNFPA's confidentiality and conflict of interest rules.
- Willingness to work under a staff augmentation modality as described in the respective section of the Terms of Reference document.

END OF TERMS OF REFERENCE FOR LOT 1: RH MEDICINES AND OTHER PHARMACEUTICALS