

12th Invitation to Manufacturers of Reproductive Health Medicines to Submit an Expression of Interest (EOI) for Product Evaluation by the WHO Expert Review Panel (ERP) for Reproductive Health Medicines

29 September 2017

1. Background

In 2011, UNFPA's Executive Board approved a new Quality Assurance Policy for Reproductive Health Medicines. The preferred approaches are for procurement of finished pharmaceutical products (FPPs) that meet the following criteria:

1. FPPs prequalified by the WHO Prequalification Programme or authorized for use by a Stringent Drug Regulatory Authority (SRA)¹; or
2. FPPs recommended for use based on advice provided by the Expert Review Panel for Reproductive Health Medicines (ERP/RHM).

2. Expert Review Panel for Reproductive Health Medicines

The ERP/RHM is an independent technical body composed of external technical experts and hosted by the Unit of Regulation of Medicines and other Health Technologies (RHT) of WHO Department of Essential Medicines and Health Products (WHO/EMP/RHT). The Procurement Services Branch of UNFPA (UNFPA/PSB) provides the Secretariat for the ERP/RHM. The ERP/RHM will be convened by WHO/EMP/RHT and review product dossiers submitted by manufacturers of FPPs that are not yet WHO-prequalified or SRA-authorized, undertake a quality risk analysis associated with the use of those products and provide written advice to the Secretariat to help making evidence based procurement decisions.

3. Eligibility criteria for ERP/RHM review

FPPs are eligible for review by the ERP if the following conditions have been met:

(a) the manufacturer of the FPP has submitted an application for prequalification of the product² by the WHO Prequalification Programme or provides written commitment to submit an application within three months from the date of approval into the ERP, and/or

(b) the manufacturer of the FPP has submitted an application for marketing authorization to an SRA, and it has been accepted for review by the SRA, and

¹ Stringent Regulatory Authority (SRA) means a regulatory authority (in case of the European Union both EMEA and national competent authorities are included) which is:

- a) a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or
- b) an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or
- c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.

For more information:

https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

² Kindly note that the product submitted/to be submitted to the PQP or for SRA marketing authorisation must be from the same manufacturing site as the one submitted to the ERP process.

(c) the FPP is manufactured at a site that is compliant with the standards of Good Manufacturing Practice (GMP) that apply for the relevant product formulation (as verified after inspections by parties such as, but not limited to, SRA, WHO Prequalification Programme or any inspectorate participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)).

4. Reproductive health medicines included in this 12th Invitation for EOI for ERP for RH Medicines

Interested manufacturers are encouraged to submit documentation for recommended dosage forms and strengths, as specified below, of reproductive health medicines in the following category:

1. Injectable hormonal contraceptives

- Medroxyprogesterone acetate + estradiol cypionate, injection 25 mg + 5 mg.

5. Basis of review process

The ERP will assess the complete ERP dossier. Risk assessment is based on the following major product attributes of submitted products:

- GMP status of the manufacturing site(s)
- API source and quality
- FPP manufacturing process and FPP quality specifications
- Stability data
- Evidence of safety and efficacy (e.g. bioequivalence data)

6. Time limitation

If the ERP issues a positive opinion, any subsequent recommendation for procurement by UNFPA with regard to an FPP will be valid for a period of no more than 18 months (“validity period”), or until the FPP is WHO-prequalified or SRA-authorized, whichever is the earlier. However, the Secretariat may, in its sole discretion, request the ERP to consider extending the validity period for up to an additional 12 months if the FPP is not yet WHO-prequalified or SRA-authorized within the validity period. UNFPA may refer more than one request for such an extension to the ERP and in this case a new ERP dossier has to be submitted. Any advice from ERP with regard to extension of the validity period will be based on ERP’s evaluation of the new dossier and progress of the FPP dossier in the PQP or SRA pipeline.

7. How to submit an EOI

In order to submit an Expression of Interest for product evaluation, the manufacturer must submit the following:

- A covering letter expressing interest to submit the product to ERP for review.
- A letter about submitting/accepting the dossier for assessment from the WHO Prequalification of Medicines Programme or an SRA confirming that the product application has been accepted for review.

- Documentation related to the GMP status of the FPP manufacturer, i.e. evidence of GMP compliance issued by WHO PQP, SRA or PIC/S member regulatory authority and, if applicable, manufacturer is strongly encouraged to submit inspection report even if the outcome may be negative.
- A completed questionnaire with annexes (see attached on UNGM, The Interagency Finished Pharmaceutical Product Questionnaire based on the model quality assurance for Procurement Agencies).
- A full set of the analytical test methods including Standard Test Procedures (If non-pharmacopeia).
- Two non-returnable product samples as requested in Section 1.7.1 of the questionnaire.
- Electronic copies of the submission.

The UNFPA Secretariat will screen the submissions for completeness. Incomplete submissions will not be forwarded to the ERP/RHM Coordinator at WHO.

All documentation must be provided in two formats:

- o One digital copy (CD)
- o One hard copy

Submissions should be addressed to the UNFPA office in Copenhagen, as follows:

UNITED NATIONS POPULATION FUND
 United Nations City
 51 Marmorvej
 2100 Copenhagen
 Denmark

REF: ERP for Injectable Hormonal Contraceptives, UNFPA/DNK/EOI/17/030.

Attention: Seloi Mogatle

8. Deadline for submissions:

All submissions must reach the UNFPA reception in Copenhagen by Thursday, **15 November 2017, at 17.00h (Copenhagen time).**

9. Further information and contact details

Any questions related to the review processes should be addressed to Ms. Seloi Mogatle at mogatle@unfpa.org.

10. United Nations Global Marketplace

All the information in this document, as well as eventual clarifications, will be made public in the UNGM website (www.ungm.org).