Quality Assurance Policy for Reproductive Health Medicines

PSB Copenhagen
Effective date: 04 April 2011

UNFPA Quality Assurance

1. RH Medicines included in the WHO Expression of Interest for Prequalification of Medicines Programme (contraceptives) (2.3.1)

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a) Prequalification Programme

b) ERP (2.3.1 a)

c) Internal Technical Committee Review recommendation (2.3.1 b)

2. Other Medicines (2.3.2)

⇨ Internal Technical Committee Review recommendation (2.3.1 b)

1 United Nations Population Fund

The United Nations Population Fund, UNFPA, is the lead agency within the UN system for the procurement and distribution of reproductive health commodities.

For more than 30 years, UNFPA has been procuring contraceptives and essential medicines to support reproductive health programmes in developing countries.

1.1 Procurement Service

UNFPA Procurement Services Branch (PSB) is responsible for UNFPA procurement operations and provides support to a large range of organizations and institutions from all over the world. These include UNFPA field offices, Governments, NGOs, World Bank borrowers as well as other UN organizations. For further information on UNFPA procurement, please refer to:

http://www.unfpa.org/public/home/procurement

1.2 Procurement Mission

UNFPA's procurement mission is:

- to provide access to impartial expert advice,
- encourage supplier neutrality in procurement,
- to respond quickly to urgent and emergency requests and
- to offer quality goods and services meeting internationally acceptable quality standards and appropriate quantities at the right price, at the right place and at the right time for use in projects.

1.3 Harmonization of quality assurance systems with other UN agencies and international organizations

To ensure standardization of quality standards, this Quality Assurance policy has been harmonized with other UN agencies and international organizations involved in the procurement of medicines, including the Global Fund and the Global Drug Facility.

UNFPA will continue to collaborate with relevant technical partners to ensure application of recommended quality tools and procedures within the UN system.

2 Quality Assurance Policy

2.1 Policy statement

UNFPA's mission achievement is significantly based on the procurement performance and therefore procurement quality. Hence, UNFPA values the importance of the quality of Reproductive Health (RH) medicines that are supplied to countries. Through joint efforts with third parties, who have available necessary expertise, UNFPA promotes the availability of affordable RH medicines that meet adequate and internationally recognized quality standards. The standards prescribed in this policy define UNFPA procurement of RH medicines.

Because of the different nature, risk benefit, standards and technical approaches in relation to different categories of RH medicines, individual parts of the policy are dealing with specific product categories.

More specifically, section 2.3.1 refers to contraceptives and reproductive health medicines, which are the RH Medicines included in the Expression of Interest in the WHO Prequalification of Medicines Programme, and section 2.3.2 includes all other medicines procured by UNFPA that are not included in the prequalification programme.

2.2 Clinical criteria

a) Compliance with Essential Medicines List and Standard Treatment Guidelines

UNFPA prioritizes procurement of RH medicines, which appear in the WHO Model List of Essential Medicines and Standard Treatment Guidelines, the WHO Reproductive Health Guidelines and the WHO Integrated Management of Pregnancy and Childbirth (IMPAC) guidelines. For further information on the Model List of Essential Medicines, please refer to:

http://www.who.int/selection_medicines/list/en/index.html

b) Dealing with non-catalogued medicines

Under certain conditions when organizing tenders, medicines that are only included in national Essential Medicines List (EML) or national treatment guidelines and not listed in the WHO EML may be procured. This will be done following a detailed technical justification for selection of that medicine, which will be reviewed and approved by Technical Division.

2.3 Quality standards

To ensure the safety, efficacy and quality of all the medicines procured by UNFPA, their product dossiers must have been assessed and found acceptable.

The frame of reference/background reference to this QA system is set by all the applicable quality standards and guidelines published in the WHO Technical Report Series.

All medicines procured by UNFPA need to be authorized for importation and use by the relevant Medicines Regulatory Authority (MRA) in the country where they will be used. In addition, the relevant standards should be met for the particular category of medicines as described in 2.3.1 and 2.3.2 below:

2.3.1 Procurement of medicines which are included in the Expression of Interest under the WHO Prequalification of Medicines Programme (contraceptives)

UNFPA procures only RH medicines, which are invited for WHO Prequalification that meet the following quality standards:

i. Prequalified by the WHO Prequalification of Medicines Programme or authorized for use by a Stringent Regulatory Authority (SRA)[1]; or
ii. Recommended for use by an Expert Review Panel (ERP), as described in Section 2.3.1 (a) below; or
iii. Recommended for use by the Internal Technical Committee Review Panel as described in Section 2.3.1 (b) below.

For a list of RH medicines that are included in the Expression of Interest under the Prequalification of Medicines Programme, please refer to: http://who.int/prequal/

Note: For the purpose of UNFPA procurement, products prequalified by the WHO Prequalification of Medicines Programme or authorized for use by a Stringent Regulatory Authority are seen as equivalent.

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[1] *Stringent Regulatory Authority (SRA)*

For the purpose of this policy, an SRA is the medicine regulatory authority in a country which is (a) a member of the ICH (EU member, Japan and USA); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

In the case that there is only one or no RH medicine product requested for procurement available that meets quality standard set out in (i) above, other medicines must meet the standard in (ii) or (iii) above as described in Section 2.3.1 (a) and Section 2.3.1 (b) below respectively.

a) Expert Review Panel process

This process consists of forming a panel of experts in order to assess the potential of recommending the use of a RH medicine that has not yet been WHO Prequalified or SRA authorized, though actions have been taken by the manufacturer to achieve this goal. Taking experts' conclusions as starting point, the Expert Review Panel will deliver a recommendation to UNFPA.

Both the review process and the procedures followed to reach a conclusion on a position regarding recommendations to procure will be made open and public.

In the case that the ERP recommends the product for public sector procurement, the support for procurement of this product shall be valid for a maximum period of 12 months or until the product is WHO prequalified or SRA approved, whichever is earlier.

b) Internal Technical Committee Review recommendation

A UNFPA Technical Committee Review panel will manage the selection of the products for procurement where there is no medicine available that meets the quality standards set out in 2.3.1 (i) or 2.3.1 (ii) above.

The implementation of the Internal Technical Committee Review recommendation is a transitional arrangement in the interest of public health and to ensure uninterrupted supply of RH medicines.

Manufacturers interested in supplying to UNFPA, will be asked to provide detailed information focusing on specified technical data. Once those data are received, the Technical Experts will perform risk-assessment on the basis of information obtained and available from other sources. Key criteria applied in the assessment will be based on status of GMP compliance, available information about active raw materials, reference to pharmacopeia standards, stability data, countries where product is registered, extent of quality control applied, and UNFPA experience with manufacturer.

UNFPA will make the requirements of this assessment publicly available.
Outcomes of assessment by the Internal Technical Committee will be the basis for decision about the length of contract with manufacturer and extent of laboratory control of supplied medicines.

Length of transition period for individual categories for medicines will be determined according to availability of quality assured products (in line with criteria under WHO prequalification or SRA approval).

Note: Under 2.3.1a and 2.3.1b, after 12 months, the possibility of extension will be considered provided there is evidence of progress with WHO product dossier acceptance and/or assessment for prequalification. Manufacturers will be eligible for only one or the other and can't use both processes.

2.3.2 Procurement of medicines, which are not under the WHO Prequalification of Medicines Programme (other medicines)

Other medicines procured by UNFPA which are not included in the Expression of Interest under the WHO Prequalification of Medicines Programme will be managed by the UNFPA Internal Technical Committee. The risk assessment will follow the criteria of: status of GMP compliance; quality assurance of Active Pharmaceutical Ingredients and the Finished Pharmaceutical Product; reference to the latest edition of British, United States, European or International Pharmacopoeias if such a Monograph exists and stability data.

3 Monitoring quality of RH medicines

3.1 Assuring quality

The final product quality is controlled by UNFPA at different steps of the procurement-distribution process.

UNFPA monitors the performance of suppliers with respect to product and supply chain quality and collaborates in this respect with Medicines Regulatory Authorities in recipient countries and with other partners.

Manufacturers must submit to UNFPA the results of manufacturer's own quality control laboratory tests for each batch of all the RH medicines procured by UNFPA.

UNFPA will coordinate where necessary, pre-shipment inspection, and independent sampling and quality control testing.

Suppliers are requested to provide medicines that still have more than 75% of shelf life at time of delivery. UNFPA reserves the right to refuse any medicinal products with an expiry date of less than 75% of shelf life.

3.2 Monitoring quality

The quality of RH medicines procured by UNFPA is independently monitored at different points in the supply chain. The sampling and testing protocol and standard operating procedures for quality control testing is based on and will vary according to the category source of the product as described in Section 2.3.1 and Section 2.3.2 above.

3.2.1 Pre-shipment quality testing

Except for WHO prequalified and SRA authorized medicines, randomly selected samples will be tested by independent UNFPA designated Quality Control Laboratories (QCL) prior to the delivery of the batches. To ensure the quality of independent quality control testing, UNFPA only uses the services of QCL that meet one of the following criteria:

a) Prequalified by WHO Pre-qualification Programme, or

b) Accredited in accordance with ISO 17025.

3.2.2 Post-shipment quality monitoring

Medicines Regulatory Authorities (MRA) have the authority to conduct post-shipment testing according to their national drug monitoring regulations. As such, UNFPA will respect any systematic laboratory testing those countries and their national regulatory authorities deem necessary.

UNFPA actively supports and encourages compliance of testing laboratories with Good Practice for QCLs as demonstrated by WHO prequalification or accreditation according to ISO 17025.

Manufacturers are expected to report to UNFPA any information concerning change in safety profile of supplied medicines, which is available to them. UNFPA reserves the right to be in contact with national MRAs concerning issues related to quality, safety and efficacy of procured medicines and is willing to participate in post delivery monitoring activities in collaboration with MRAs, WHO and other relevant partners.

3.3 Solving disputes

In the event of testing results conducted by UNFPA designated independent QCLs, either during pre-shipment or post-shipment testing that are non-conforming to specifications as per indicated pharmacopoeia standards, the manufacturer will be required to investigate the discrepancy and provide a report.

In case of non-compliance, either in the quality of the product or appropriate packaging or agreed labeling, the manufacturer will be requested to replace the complete batch at manufacturer's own cost or reimburse UNFPA as well as and take appropriate actions to eliminate risks to health of users.

3.4 Managing product recalls

UNFPA reserves the right to suspend procurement of medicines in case of identification of inferior quality and inform publicly where applicable, the MRA and patients who may be affected.

In the event that UNFPA in co-operation with MRA in supplied countries decides on product recall, the manufacturer will organize this recall and necessary associated activities or manufacturer will compensate recall expenditures to UNFPA.

4 Revisions to this policy

This QA policy comes into effect on 04/04/2011 and will be subject to revisions periodically or as deemed necessary.

All contracts and contract extensions related to procurement of medicines signed by UNFPA after the day this policy has come in the effect will be signed in compliance with this document.