

Annex 9

World Health Organization/United Nations Population Fund Prequalification Programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices

Background

The report of the Fifty-third meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSP) in 2018 (1) stated the following:

Ms Seloï Mogatle and Dr William Potter from the United Nations Population Fund (UNFPA) gave an update on the prequalification guidance for contraceptive devices and condoms. The UNFPA had contacted WHO to inquire how best to start a process to update the relevant texts that we adopted by the ECSP and published in 2008 (2, 3). The Expert Committee agreed to the importance of updating these materials in view of the changes in the contraceptive field globally over the previous decade. The two organizations committed to work together to bring the documents up to date. It was suggested by UNFPA to separate out the current existing procedure for condoms to include the following aspects:

- 1. prequalification guidance for contraceptive devices;*
- 2. prequalification programme for male latex condom and annexes;*
- 3. technical specification for male latex condom and annexes;*
- 4. male latex condom prequalification inspection aide memoire;*
- 5. condom quality assurance and annexes;*
- 6. guidance on testing male latex condoms;*
- 7. condom storage and transportation;*
- 8. post-market surveillance of condoms;*
- 9. public assessment reports for contraceptive devices – condoms and intrauterine devices.*

UNFPA also raised the issue of specifications for lubricants (both water-based and silicon-based), which needs to be considered when developing the new guidelines.

The Expert Committee supported the development of the relevant documents for prequalification of condoms in consultation with the WHO Secretariat and their preparation for public consultation and took note that they will be reported back to the Expert Committee.

As agreed at the ECSP meeting in October 2018, UNFPA and WHO have separated out different aspects of the current procedure for contraceptive devices and condoms.

All related documents were restructured and revised in the first half of 2019, then sent out for public consultation in July 2019. Comments received were reviewed by a group of specialists in October 2019, before being presented to the ECSP. This is one of the three adopted by the Fifty-fourth ECSP meeting to replace the previous guidance document.

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1. Introduction

The United Nations, through its procurement agencies, supplies medicines and other health products to countries throughout the world, in order to improve access to a choice of products of acceptable quality, safety and efficacy.

The World Health Organization (WHO), United Nations Population Fund (UNFPA) and other key partners developed an evidence-based list of essential medicines for reproductive health (2006) (4), which was subsequently approved by the WHO Expert Committee on Selection and Use of Essential Medicines. From this list, and the recommendations of members of the Reproductive Health Supplies Coalition, it was agreed that WHO would include a core group of contraceptive essential medicines in the Prequalification Programme, the implementation of which began in 2006. As part of this activity, it was agreed that UNFPA would take responsibility for the prequalification of copper-bearing intrauterine devices and male latex condoms, and that the UNFPA scheme would be harmonized with that of the WHO Prequalification Programme.

This document describes the implementation of the WHO/UNFPA Prequalification Programme for contraceptive devices (male latex condoms, female condoms and intrauterine devices).

The Prequalification Programme was approved in principle and subject to confirmation following an external review for publication by the Forty-second meeting of the Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in October 2007 (2).

The Prequalification Programme is supported by a specific UNFPA management system with detailed standard operating procedures (SOPs).

The WHO/UNFPA Prequalification Programme involves the following key activities:

- the evaluation of documents submitted in response to an invitation for expression of interest (EOI);
- the inspection of each manufacturing site per product;
- product testing;
- the review of testing and inspection reports to make a decision about the acceptability of each product and its specific manufacturing site; and
- the periodic reassessment of the prequalification status of products and manufacturing sites.

1.1 Objectives

The overall objective is to implement a scheme to prequalify manufacturers of contraceptive devices of assured quality, at specific manufacturing sites, for

procurement by United Nations agencies and other bulk procurement agencies. Specific objectives are to:

- promote the procurement of contraceptive devices from manufacturing sites that have been ascertained to have the capacity to produce good quality products;
- establish a system that promotes the procurement of good quality products that retain their effectiveness throughout their stated shelf-life and conform to the latest edition of the relevant international standard for the product;
- broaden the base of suppliers for contraceptive devices that are deemed acceptable, in principle, for procurement by United Nations agencies and other bulk procurement agencies; and
- maintain and publish the list of prequalified suppliers.

2. The Prequalification Programme for reproductive health devices

2.1 Eligibility to participate

The Prequalification Programme is intended for manufacturers who carry out all key manufacturing steps, as specified by UNFPA in the call for an EOI referred to in [Section 2.2](#).

For male latex condoms, this includes manufacturers that undertake the processes of formulation, compounding and dipping, lubrication, and testing, as well as manufacturers using pre-vulcanized latex and who undertake at least the final assembly, testing and packaging of the finished product.

For female condoms, this includes manufacturers that undertake the processes of formulation, compounding and dipping, lubrication, and testing, and who undertake at least the formation of the sheath, testing and packaging.

For intrauterine devices, this includes manufacturers that undertake the process of moulding, assembly, packaging and control of sterilization. One or more of these processes may be carried out on a contract basis but the manufacturer retains overall responsibility for product quality.

The Prequalification Programme does not apply to agents, distributors or suppliers engaged only in testing, lubricating and primary packaging.

2.2 Application for prequalification: expression of interest

2.2.1 Calls for and submission of expressions of interest

Invitations to interested parties to submit EOIs are published at regular intervals on the UNFPA website.

The invitation is open and transparent and invites manufacturers and/or their agents, as described in [Section 2.1](#), to submit EOIs for the products listed in the invitation. The manufacturers should submit their EOIs to the UNFPA focal point, with the relevant information requested in the invitation. Manufacturers that are applying for a requalification/reassessment should submit the EOI the year before the re-inspection is to take place (see [Section 2.9](#)). If a manufacturer has more than one site, each site must submit a separate application. The manufacturers will be given a specified period from the time of publication of the advertisement to submit their responses. The information must be submitted in English (see [Section 2.10](#)).

UNFPA will receive and record the EOI from each manufacturer and issue an acknowledgement of receipt.

WHO and UNFPA will provide further guidance on the submission of documentation for prequalification and make such guidance available on the UNFPA and WHO websites.

When submitting an EOI, the manufacturer should send the following items to the UNFPA focal point:

- a covering letter expressing interest in participating in the WHO/UNFPA Prequalification Programme and confirming that the information submitted in the summary technical documentation (STED) is complete and correct; refer to [Appendix 1](#) for a sample covering letter;
- an STED as specified in the WHO/UNFPA technical specification for male latex condoms, female condoms or intrauterine devices for submitting product data and information; and
- 10 product samples in their primary package, as examples of products produced, for each type mentioned in the STED (if applicable).

The STED must be accompanied by copies of all current certifications/accreditations; all manufacturing licences/registrations held; a copy of the company registration; copies of certificates and relevant documentation as applicable in the country of manufacture; documentation of the principal place of incorporation (for those that are corporations); specific certification/licences required in the country for manufacturing and exporting; and other legal documents, such as trading certificates.

The documentation must be submitted in English, as described in [Section 2.11](#). Documents that are not in English must be submitted with certified translations. The manufacturer must provide an electronic version (CD or USB key to be sent by courier or registered mail or email) of this material.

2.2.2 Assessment of documents submitted

The aim of assessment of the submitted documentation is to determine whether the manufacturer is certified to ISO 13485 (5) and other appropriate ISO standards; has appropriate regulatory approvals, manufacturing capacity, factory documentation and legal status; and is capable, in principle, of meeting the WHO/ UNFPA specification with respect to product quality and safety, to warrant inspection by UNFPA.

2.2.2.1 Initial screening of documentation

UNFPA will aim to screen the documentation within 30 days of the closing date for receipt of responses, to ascertain whether or not it contains all the required information.

If the submission is incomplete, the manufacturer will be informed and requested to complete the STED within a specified time period. If the STED remains incomplete, it may be rejected.

STEDs that are considered complete following the administrative screening will be retained by UNFPA for evaluation.

UNFPA will exchange letters with the manufacturer covering provisions of confidentiality; the process of assessment of submitted information; and the scheduling and procedure of the site inspection.

2.2.2.2 Assessment of the summary technical documentation

UNFPA will appoint suitably qualified and experienced experts to complete the assessment of the STED within 90 days of the closing date for receipt of responses.

The assessment of the submitted documentation will be done in accordance with SOPs established by UNFPA for that purpose. To ensure uniformity in the evaluation and timeliness of assessment activities, UNFPA will, if needed, provide training to the assessors on the procedures that are specific to UNFPA.

In making its assessment, UNFPA may take into account information submitted by the manufacturer during previous applications that may be in UNFPA's possession, including results from previous site inspections and laboratory test results on the relevant products produced by the manufacturer.

UNFPA aims to advise the manufacturers of the outcome of their assessment of the documentation within 30 days after its completion. If applications are found to be in compliance with the requirements of UNFPA, as detailed in the operational guidance for the product and on the WHO and UNFPA websites, the manufacturing site will be scheduled for inspection.

2.2.2.3 Technical experts hired by UNFPA

Profile

Document assessments and inspections are carried out by technical experts appointed by UNFPA. The technical experts are selected through an international competitive bidding process to select individuals that have documented qualifications, detailed knowledge of the process for manufacturing contraceptive devices, experience in auditing and quality management systems, and specific experience inspecting sites manufacturing contraceptive devices.

The document assessment and inspection may include one or more experts. The assessor may be responsible for subsequent inspections of the manufacturing site, depending on the contraceptive device. The experts must comply with the confidentiality and conflict-of-interest rules of UNFPA, as laid down in [Sections 3 and 4](#) of this guidance document.

2.3 Site inspection

UNFPA will plan and coordinate inspections at the manufacturing sites to assess:

- the manufacturing facilities;
- the manufacturing process;
- the quality management systems; and
- product quality

for compliance with the requirements of the WHO/UNFPA specification and good management practice, including the international standards relevant to the product.

2.3.1 Inspection team

The inspection will be performed by a team of inspectors consisting of experts appointed by UNFPA, who will conduct the assessment on behalf of UNFPA. The inspectors must have documented qualifications, detailed knowledge of manufacturing processes, expertise in auditing and quality management systems, and specific experience in inspecting condom and intrauterine device manufacturing sites. The inspectors must comply with the confidentiality and conflict-of-interest rules of UNFPA, as detailed in [Sections 3 and 4](#) of this guidance document. To ensure uniformity in inspection procedures, UNFPA has prepared an SOP and, if necessary, can provide training to these experts.

Where possible, UNFPA will appoint at least one inspector who is able to communicate in and read the local language. Failing this, an interpreter selected by UNFPA will be used. One member of the team will be designated by UNFPA as the “lead inspector” and will be responsible for directing the on-site inspection

activities and production of the report. The team may include observers from UNFPA. UNFPA will advise and seek the involvement of the national competent body in the on-site inspection.

UNFPA will advise the manufacturer, in advance, of the composition of the team performing the site inspection and the identity of each inspector. The manufacturer has the opportunity to express possible concerns regarding any of the inspectors, to UNFPA prior to the visit. If such concerns cannot be resolved in consultation with UNFPA, the manufacturer may object to a team member's participation in the site visit. Such an objection must be made known to UNFPA by the manufacturer within 10 days of receipt of information on the composition of the proposed team. UNFPA will consider the objection and, if it is upheld, a replacement inspector will be appointed.

In order to ensure a standardized approach, each team will perform the inspections and report on its findings to UNFPA, in accordance with the SOPs established by UNFPA for that purpose.

Information submitted in response to the invitation for EOI and the assessment report will be made available to the inspectors. All inspectors must comply with the confidentiality and conflict-of-interest rules of UNFPA, as detailed in [Sections 3 and 4](#).

2.3.2 Scope and scheduling

Prior to the inspection, the manufacturer will be informed of the scope of the inspectors' planned activities. The key components of the inspection are described in the operational guidance of the relevant technical specifications of the product (6–8) and on the WHO and UNFPA websites. The inspection may not be limited to these components. Manufacturers must be prepared to show the inspectors all aspects of the facility, including records and data that relate to the production of the condoms and intrauterine devices.

UNFPA aims to advise the manufacturer of the date of inspection at least 30 days in advance. UNFPA and the inspectors will make efforts to accommodate reasonable requests by the manufacturers and national regulatory authorities to change the date of inspection.

UNFPA will inform the manufacturer that the inspectors may request copies of specific documents for review during inspection and may request permission to take photographs during the inspection, subject always to considerations of confidential information as referred to in [Section 3](#) of this document.

2.3.3 Transparency

The inspection team is paid by UNFPA to inspect the facilities and the members are reimbursed by UNFPA for their hotel and transport expenses.

The manufacturer will not pay for hotel accommodation or make any payments for or to the inspectors and/or UNFPA staff. The manufacturer may be requested to assist in making reservations at an appropriate hotel and arrangements for local transportation between the hotel and manufacturing facilities.

The members of the inspection team cannot accept any gifts from the companies they visit. UNFPA requires that manufacturers do not make any offers of gifts of whatever value to the inspectors and/or UNFPA staff.

By participating in the Prequalification Programme, the manufacturer agrees to allow full access to:

- any of the facilities that are in any way involved in the production, packaging and storage of the product(s) concerned; and
- all documentation related to that production.

If such access is not provided, the inspection will not be completed, and the manufacturing site and specific products cannot be prequalified.

Any evidence of fraud or serious omissions by the manufacturer in the initial assessment procedure or the inspection will lead to termination of the site inspection.

2.4 Product testing

Products will be sampled for independent testing according to the sampling requirements for prequalification testing specified in the WHO/UNFPA technical specification: *WHO/United Nations Population Fund technical specifications for male latex condoms* (6); *Female condom: generic specification, prequalification and guidelines for procurement* (7); or the *TCu380A intrauterine contraceptive device: WHO/UNFPA technical specification and prequalification guidance* (8).

Products will be sampled for independent testing before or after the inspection, under the supervision of, or by, an independent sampler appointed by UNFPA or by the inspectors at an appropriate point during the site inspection. As a component of their prequalification application, manufacturers shall submit a copy of their production plan for the coming year, to enable UNFPA to communicate the number of samples from each production lot. The manufacturers should retain samples for prequalification testing and/or schedule the inspection during a time when sample lots will be available for sampling. Sampling and testing will be conducted in accordance with the requirements detailed in the WHO/UNFPA technical specifications (6–8). All product testing will be undertaken by independent test laboratories selected by UNFPA, of defined and documented competence and experience, as demonstrated by accreditation to the current ISO 17025 standard (9) with testing of contraceptive product within the scope of its accreditation. The sample will be packed and sealed by the inspector or the independent sampler,

as appropriate. The inspectors may take the sample with them or arrange for the manufacturer to have the sealed box sent to the selected laboratory by courier, at UNFPA's expense.

The manufacturer will be provided with a copy of this test report.

2.5 Reporting and decision to prequalify

At the conclusion of the inspection, the inspectors will prepare a brief written summary report outlining the key findings and observations discussed with the manufacturer during the site inspection. A copy of this report will be provided to the manufacturer.

Manufacturers should not submit corrective actions to UNFPA in response to this summary report but only in response to the official inspection report that is issued. The official inspection report prepared by the inspection team will be issued to the manufacturer by UNFPA 4–6 weeks following the inspection.

The report will indicate one of the following recommendations:

- prequalify the product manufactured at a specific site without conditions. This will only be the case when there is no evidence that corrective action is required;
- require the manufacturer, where deemed necessary, to undertake specified corrective and preventive action(s) (CAPA(s));
- determine that the product and manufacturing site is ineligible for prequalification (without any requirement for corrective action being offered). This will not, however, preclude the manufacturer from resubmitting an application in response to future invitations for EOIs.

If any additional information is required, or corrective action has to be taken by the manufacturer(s), UNFPA will postpone its decision on the acceptability of the site(s) involved until such information has been evaluated, or the corrective action has been taken and found satisfactory in accordance with the time frame and recommendations made by the inspectors.

The inspection report may contain nonconformities and observations. The findings of the inspection may include non-mandatory observations aimed at highlighting potential for improved manufacturing and quality management practices. Nonconformities are classified as major or minor. A manufacturer that receives a major nonconformity cannot be prequalified and, if already prequalified, its status may be suspended. A major nonconformity will require submission of corrective and preventative actions and a possible re-inspection. Minor nonconformities require corrective and preventative action to be submitted

to UNFPA by the manufacturer in the stated period, in order to achieve or maintain prequalification. Observations made by the inspectors are intended to highlight opportunities to improve quality management practices. It is strongly recommended that manufacturers consider acting upon any observations made, but prequalification is not dependent upon this.

Where UNFPA recommends corrective action, the manufacturer must advise UNFPA within an agreed period of time that corrective action has been completed and provide the relevant evidence, if required. The recommendation for corrective action may include further independent product testing or re-inspection. After review of the evidence, UNFPA will decide whether or not to schedule a further inspection.

CAPA submissions should be submitted to UNFPA electronically, in response to the official inspection report. Evidence of action shall be provided. Evidence of actions taken should be supplied to UNFPA in the form of SOPs, pictures or other appropriate formats. The files submitted shall be organized and clearly labelled. Each manufacturer will normally be permitted two rounds of CAPA reviews. The first submission of corrective and preventive actions shall be in possession of UNFPA within 90 days of receipt of the official inspection report, unless otherwise agreed with UNFPA. If a manufacturer has not successfully addressed all nonconformities raised during the inspection following the second CAPA review, the manufacturer may be asked to submit a fresh EOI for prequalification. The EOI should only be submitted when the manufacturer demonstrates compliance with the requirements of the Prequalification Programme. Any exceptions to this will be evaluated on a case-by-case basis.

If a further inspection is deemed necessary, the inspection process and assessment will be implemented in accordance with the procedure detailed in [Sections 2.3, 2.4 and 2.5](#) of this document. Any re-inspection may be at the expense of the manufacturer.

If evidence supporting mandatory improvement actions or additional information is required, or other corrective actions have to be taken by the manufacturer, UNFPA will postpone its final decision until such information has been evaluated or the corrective action has been taken and found satisfactory.

If the manufacturer has not submitted a satisfactory response within 12 months of submission of the report from UNFPA, the application will lapse and the manufacturer will need to reapply in response to a future invitation for an EOI.

UNFPA reserves the right to terminate the procedure of quality assessment of a specific product if:

- the manufacturer is not able to provide the required information; and/or

- the manufacturer is unable to implement the corrective actions in a specified time period; and/or
- the information supplied is inadequate to complete the quality assessment process.

Each manufacturer will receive a letter from UNFPA informing them of the outcome of the quality assessment process. UNFPA aims to inform the manufacturer of the results of the process within 30 days of receipt of all final reports. Manufacturers will verify the final report that is produced for accuracy. In the event of any disagreement between a manufacturer and UNFPA, an SOP established by UNFPA detailing the handling of appeals and complaints will be followed, to discuss and resolve the issue. The ownership of any of the reports produced during the course of, or as the result of, the assessment of documentation, product testing and inspection of the manufacturing site, lies with UNFPA. Thus, UNFPA shall be entitled to use and publish such reports and/or a summary of a report, subject always, however, to the protection of any commercially confidential information of the manufacturer(s).

Confidential information may include:

- confidential intellectual property, “know-how” and trade secrets (including, e.g. formulas, processes or information contained or embodied in a product, unpublished aspects of trademarks and/or patents); and
- commercial confidences (e.g. structures and development plans of a company).

Provisions of confidentiality will be contained in the exchange of letters, to be concluded before the assessment of the STED or inspection of the manufacturing site(s), between UNFPA and each manufacturer.

Notwithstanding the foregoing, UNFPA and WHO may share a summary and/or the full evaluation and inspection reports with the relevant authorities of any interested Member State of United Nations and/or WHO. Confidential information submitted by the manufacturer that is marked “confidential” will not be included in the full evaluation and inspection reports without the permission of the manufacturer.

2.6 Listing of prequalified contraceptive devices and manufacturing sites

Once UNFPA is satisfied that the quality assessment process is complete and where the STED and corresponding manufacturing site have been found to meet the prequalification requirements, the product produced at the specified

manufacturing site(s) will be listed on the WHO and UNFPA prequalification websites.

The list of prequalified contraceptive devices and corresponding manufacturing sites will be compiled and updated in accordance with an SOP established by UNFPA for this purpose.

2.7 Maintenance of prequalification status

Once the product and the corresponding manufacturing sites are included in the list of prequalified manufacturers, the manufacturer is required to advise UNFPA, within 30 days, of any matter that affects the information on which the approval was based. This includes but is not limited to:

- change of premises;
- change in production and testing equipment;
- change in senior management;
- product recalls;
- change in certifications or licences held by the manufacturer;
- reports of adverse events;
- change in device design;
- change in suppliers' key raw materials and components not previously listed in the STED;
- change in specification of raw materials, components and primary packaging materials;
- change in packaging;
- change in formulation;
- change in process and/or technology;
- change in production capacity; and
- new information about shelf-life.

It is the manufacturer's responsibility to provide UNFPA with the appropriate documentation (referring to relevant parts of the STED) to prove that the implementation of any intended variation will not have an adverse impact on the quality of the product that has been prequalified. UNFPA will undertake an evaluation of variations according to established UNFPA guidelines and SOPs, and communicate the outcome to the manufacturer. Compliance with the requirement to report changes will be checked during the reassessment inspection and processes carried out by UNFPA.

2.8 Periodic monitoring of the quality of products produced by prequalified manufacturing sites

At periodic intervals, UNFPA may, through an independent sampler, take random samples of contraceptive devices produced by listed manufacturers. Samples will be taken from intact lots stored in the manufacturer's or distributor's warehouse. The sample size will be in accordance with the current international standard for the contraceptive devices. The range of tests to be conducted will be in accordance with lot-by-lot pre-shipment compliance testing, as detailed in the WHO/UNFPA technical specification for the product.

All product testing will be undertaken by an independent test laboratory, selected by UNFPA, of defined and documented accreditation to the current ISO 17025 (9) international standard. In the event of failure to meet the established requirements for testing, UNFPA will investigate the problem and communicate this to the manufacturer.

UNFPA may request reports from consumer or regulatory authorities, or from other procurement agencies relating to the quality and supply of the prequalified contraceptive device.

Complaints communicated to UNFPA concerning contraceptive devices procured through this Prequalification Programme will be investigated in accordance with an SOP established by UNFPA for that purpose. After investigation, UNFPA will provide a written report of the complaint investigations, including recommendations for action, to the manufacturer. UNFPA will require evidence of effective action taken, where relevant.

UNFPA will make the report available to the appropriate authorities of the country where the manufacturing site is located, when necessary in the interest of public health, subject always to consideration of commercially confidential information, as referred to earlier in this document. UNFPA reserves the right to make such reports public if it considers this to be of public health importance. In addition, UNFPA reserves the right to share the full report and/or recommendations for action with WHO and relevant authorities of interested Member States of the United Nations and/or WHO. At periodic intervals, UNFPA may request a summary of the statistical analysis of product production from the manufacturer, for demonstration of continued capability to manufacture to the WHO/UNFPA technical specification. This may be accompanied by a request for selected evidence from management review, risk management, production, measurement and analysis and other records.

2.9 Reassessment of prequalified manufacturing sites – reassessment

UNFPA aims to undertake a reassessment of products manufactured at a specific site, at intervals of at least 3 years and no more than 5 years. Such reassessments

will consist of a comprehensive evaluation of documentation, site inspection and product testing, similar to the initial prequalification assessment, as determined by a risk-based assessment. Prequalified manufacturers should submit a EOI (application) for reassessment 12 months before expiry of their current prequalification status.

Reassessment may also be required in the following situations:

- if the contraceptive devices supplied by the manufacturer are considered by UNFPA or by one or more of the other United Nations agencies not to be in compliance with the agreed WHO/ UNFPA specification and requirements for pre-shipment compliance testing;
- if a complaint that is considered serious in nature has been received by UNFPA or one or more of the other United Nations agencies or organizations; and
- if there is a significant change in the manufacturing process in respect to one or more of the items listed in [Section 2.7](#).

All relevant information, including the reassessment of submitted documentation and site inspection reports, together with monitoring information, will be considered by the designated UNFPA official, and a decision will be made to:

- maintain the contraceptive device and its manufacturing site on the list of prequalified products without need for corrective actions;
- maintain the prequalification status of the contraceptive device and its manufacturing site with a requirement for corrective actions and, where agreed to by UNFPA, further product testing and/or a site inspection; or
- suspend the prequalified status.

UNFPA aims to advise the manufacturer of the result of the reassessment and make any necessary amendments to the list of prequalified manufacturing sites and products within 30 days of receipt of the data on the basis of which the decision is made. The updated list will be published on the WHO and UNFPA prequalification websites.

UNFPA will de-list any prequalified product and manufacturing site if the submitted information is subsequently found to be incorrect or fraudulent. UNFPA will issue a notice of listing and de-listing and inform the appropriate authorities.

2.10 Language

The official language of the programme is English. All documents submitted as part of an application for prequalification will be in English. If the original of any required document is not in English, the manufacturer must submit a copy of the original plus a certified translation into English. All correspondence between UNFPA and the manufacturer should be in English. All reports issued by the assessors, inspectors and UNFPA on the assessment and inspections will be in English.

Inspections will be conducted in English, with the aid of an interpreter where necessary. It is the responsibility of the manufacturer to advise UNFPA and for UNFPA to agree whether or not an interpreter is required for the inspection.

2.11 Fees

To ensure sustainability of the Prequalification Programme, UNFPA has introduced prequalification fees to contribute to the expenses of the assessments, inspections and product testing. The fees were introduced in 2019 after several consultations with manufacturers.

2.12 Resolution of disputes

If there is any disagreement between a manufacturer and UNFPA, an SOP established by UNFPA for the handling of appeals and complaints will be followed, to discuss and resolve the issue.

3. Confidentiality undertaking

The assessors and inspectors will treat all information to which they gain access during the evaluations and inspections, or otherwise in connection with the discharge of their responsibilities in regard to the above-mentioned project, as confidential and proprietary to UNFPA and parties collaborating with UNFPA, in accordance with the terms set out below.

Assessors and inspectors will take all reasonable measures to ensure that:

- confidential information is not used for any other purpose than the evaluation/inspection activities described in this document; and
- confidential information is not disclosed or provided to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

Assessors and inspectors will not, however, be bound by any obligations of confidentiality and non-use to the extent they can clearly demonstrate that any part of the confidential information:

- was known to them prior to any disclosure by or on behalf of UNFPA (including disclosure by manufacturers);
- was in the public domain at the time of disclosure by or on behalf of UNFPA (including by manufacturers);
- has become part of the public domain through no fault of theirs; or
- has become available to them from a third party not in breach of any legal obligations of confidentiality.

4. Conflict of interest

Before undertaking the work, each assessor and inspector will also (in addition to the above-mentioned confidentiality undertaking) be required to sign a declaration of interest.

If, based on this declaration of interest, it is felt that there is no risk of a real or perceived conflict of interest (or it is felt that there is only an insignificant and/or irrelevant conflict of interest), and it is thus deemed appropriate for the evaluator or inspector in question to undertake this work, he or she will discharge his or her functions exclusively as adviser to UNFPA. In this connection, each assessor and inspector is required to confirm that the information disclosed by him or her in the declaration of interest is correct and complete, and that he or she will immediately notify UNFPA of any change in this information.

References

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2. Procedure for assessing the acceptability, in principle, of male latex condoms for purchase by United Nations agencies. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-second report. Geneva: World Health Organization; 2008: Annex 2 (WHO Technical Report Series, No. 948; https://www.who.int/medicines/areas/quality_safety/quality_assurance/ProcedureAssessingAcceptabilityMaleLatexCondomsPurchaseUNAgenciesTRS948Annex2.pdf?ua=1, accessed 17 December 2019).
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Appendix 1

Letter of application for prequalification of contraceptive devices

All product summary technical documentation (STED) submitted must be accompanied by a covering letter expressing interest in participating in the United Nations Population Fund (UNFPA) prequalification process and confirming that the information submitted in the STEFD summary is complete and correct. Below is an example of such a letter.

Letter of application

Date _____

To: United Nations Population Fund
Procurement Services Branch
Marmorvej 51
DK 2100 Copenhagen
Denmark

Sir/Madam:

Being duly authorized to represent and act on behalf of [name of manufacturer] (hereinafter referred to as the “Applicant”) and having reviewed and fully understood all the information on prequalification provided, the undersigned hereby applies to be prequalified by UNFPA as a potential supplier of [indicate relevant device].

Attached to this letter are copies of original documents defining:

- the Applicant’s legal status
- the summary technical documentation (STED)
- sample products [if applicable].

UNFPA and its authorized representatives are hereby authorized to conduct any enquiries or investigations to verify the statements, documents and information submitted in connection with this application and to seek clarification from our bankers and clients regarding any financial and technical aspects. This letter of application will also serve as authorization to any individual or authorized representative of any institution referred to in the supporting documentation to provide such information deemed necessary and requested by yourselves to

verify statements and information provided in this application or with regard to the resources, experience and competence of the Applicant.

The Applicant declares that all the information provided with the application is valid.

Name of Applicant [Organization] _____

Name of Responsible Officer _____

Signature _____

Position/Title _____ Date _____

