



Technical Working Group on Specifications of Contraceptive Devices and Personal Lubricants

Terms of Reference

Sept 2020

I. Background

The United Nations, through its procurement agencies, supplies medicines, medical devices and other health products to countries all over the world in order to improve access to a choice of products that meet standard specifications and are of internationally acceptable quality, safety and efficacy. The purchase of poor-quality condoms will adversely affect every aspect of condom promotion and programming.

UNFPA manages the Female Condom and Male Latex Condom Prequalification Programmes for the United Nations system. The World Health Organization delegated the management of these programmes to UNFPA in 2005, when it was agreed that UNFPA would take responsibility for condom prequalification on behalf of the global reproductive health community while the World Health Organization would continue its work on global norms and standard setting and, together with key partners, develop recommended international specifications and technical and procurement guidelines for condoms. Prequalification for condoms and IUDs has since been harmonized with the WHO Prequalification of Medicines Programme. Currently, however, there is no expert committee responsible for specifications and guidelines on contraceptive devices and personal lubricants. This is a new and additional area for harmonization. Therefore, the WHO/UNFPA prequalification programmes requested the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSP) to provide oversight. The establishment of an informal technical working group to advise the ECSP on updating the prequalification guidance documents was discussed. This document provides a Terms of Reference (ToR) for the group.

II. Objective of the informal working group

The Technical Working Group on Specifications of Contraceptive Devices and Personal Lubricants is mandated to:

- Determine the scope and coverage of the documents
- Review and provide comments and suggestions on the documents for technical specifications of contraceptive devices and personal lubricants developed by UNFPA
- Review the feedback received on the various working documents during the public consultation and to provide advice to the ECSP

III. Membership of the informal working group

Members of the group will be technical staff working in the area of contraceptive device regulation, quality assurance, research at UNFPA and the World Health Organization. Other members will be drawn from national regulatory authorities, universities, consumer groups, other international organizations and individual experts. The overall membership should ensure a balance among fields of expertise, with at least one third from low- and middle-income countries, with the total number of members not to exceed 15. Membership may be increased or decreased as the exigencies of the work require and based on available resources. Individual members are required to sign a declaration of conflict of interest prior to participating in the discussions.



Persons from the manufacturers of contraceptive devices and personal lubricants may not be members of the technical working group, but may be invited to give individual specific comments as the need arises. They also may be invited in the public consultation for the dissemination and review process as important stakeholders.

The Secretariat may also invite other agencies or individuals as resource persons or observers as the need for them arises.

The different persons engaged in the development of the documents shall be recorded and duly acknowledged in the main output documents of the group (including their specific roles and conflicts of interest, if any).

IV. Secretariat of the technical working group

WHO/UNFPA prequalification programmes team serves as the Secretariat to the Working Group.

V. Composition of technical working group

The group will be composed of:

- UNFPA – three members
- World Health Organization – one member
- National Regulatory Authorities – six members
- Academia – two members
- Private sector – one member
- International organizations – one member
- Individual experts – one member

VI. Organization of work

The group will work regularly through electronic exchanges and will have at least one meeting every year, either virtually or in person. Other meetings will be convened on the basis of need, specific tasks to be accomplished and available resources. All decisions of the group will be documented, recorded and circulated among members.

The main output of the group will be the publication of two documents: the technical specifications document on contraceptive devices and the technical specifications document on personal lubricants. The output may be submitted to WHO ECSSP for approval prior to publication or under the UNFPA Publications Committee. Other outputs may include specific papers and publications emerging from the review of the relevant literature, and for guidance on implementation.

VII. Expected duration

The work of the Technical Working Group on Specifications of Contraceptive Devices and Personal Lubricants is ongoing. This ToR will be reviewed and updated as and when needed.

The work of the group would be primarily completed once the described main output documents have been published. A few members of the group may be asked to support dissemination activities related to the documents.

VII. Resources

UNFPA will fund activities of the working group. The funding will be governed by UNFPA policies.