

FEES for WHO/UNFPA PREQUALIFICATION of CONDOMS AND IUDs



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TABLE OF CONTENTS

Background	2
Sustainable funding for prequalification	3
Consultation with manufacturers	4
Proposed Fee Model	4
Fee structure	4
Implementation of fees	5
Monitoring and evaluation	5

1 Background

Since 2006, all these activities have been performed and paid for by the UNFPA Supplies programme and the GRI budget. No core resources have been provided to fund staff. As austerity measures are being put in place, resources in 2017 have been reduced to a minimum meaning that UNFPA is no longer able to sustain the WHO/UNFPA Prequalification Programmes without resorting to other mechanisms of funding.

It should be emphasised that this programme is very important for UN agency procurement, International procurers, NGOs and Member States as the lists of prequalified manufacturers are used by all these stakeholders as a reliable source for procurement of contraceptive devices. The programme ensures that condoms and IUDs that meet internationally acceptable standards are available for procurement by stakeholders. The gains that have been made in the fight against HIV infection, other sexually transmitted infections and prevention on unwanted pregnancies will be lost if the prequalification program was to be discontinued due to lack of funding.

UNFPA manages the prequalification programme and the organisation's roles are listed below:

Major Activities	UNFPA's Role
Management of the Prequalification programmes	<ul style="list-style-type: none"> - Planning and providing strategic support - Maintains pool of qualified industry experts and inspectors
Development of technical specifications for condoms and IUD	<ul style="list-style-type: none"> - Gathers input from global stakeholders to assess, identify and implement improvements for product specifications
Development of technical guidance on prequalification of condoms and IUDs	<ul style="list-style-type: none"> - Gathers input from global stakeholders to assess, identify and implement improvements for guidance and policy documents for condoms and IUDs
Assessment of the technical file of the device	<ul style="list-style-type: none"> - Finalizes reports, maintain records and documentation - Preliminary screening of technical files
Inspection of the manufacturing site	<ul style="list-style-type: none"> - Prepares annual inspection plan - Participates in inspections to ensure uniformity and that they are conducted according to WHO/UNFPA guidelines - Monitors status of inspection recommendations
Testing of the device for prequalification purposes	<ul style="list-style-type: none"> - Ensures testing is done to international standards

Stakeholder collaboration activities	<ul style="list-style-type: none"> - Convenes partners around the agenda of quality of condoms and IUDs - Leads global harmonisation of specifications - Develops guidance for quality assurance of condoms and IUDs
Coordination of a network of national laboratories for condom testing	<ul style="list-style-type: none"> - Develop and implement training workshops - Sustains network of contacts for information sharing of quality issues
Continuous quality monitoring and management of quality complaints for prequalified manufacturers	<ul style="list-style-type: none"> - Retains data - Monitors trends - Conducts investigations
Maintenance of Member States collaboration programme	<ul style="list-style-type: none"> - Facilitates information sharing among member states - Facilitates adoption of harmonised specifications - develops guidance for regulation and quality assurance of condoms and IUDs

2 Sustainable funding for prequalification

Since its inception the programme has been funded by donor community and now there are calls for sustainable sources of funding. To reduce the cost of running the programme UNFPA is relocating two staff members from Copenhagen to Bangkok. In line with other WHO Programmes**, UNFPA will introduce fees for manufacturers.

5 Consultation with manufacturers

UNFPA consulted with manufacturers on the sustainability of the prequalification of condoms and IUDs. UNFPA prepared a draft fee structure for input by manufacturers. The fee structure below and the attached frequently asked questions were refined based on inputs from manufacturers.

6 Proposed Fee Model

After consultation with manufacturers the staggered fee structure, where manufacturers pay a prequalification or requalification fee and pay an annual retention fee is the better option. This will ensure that manufacturers are not overburdened by one off fees. Considerations to be made of the fee structure will include complexity of the product, business volumes related to prequalification or a flat structure.

7 Fee structure

The fee structures already being applied by WHO are:

- Once off fee at application for prequalification with a reduced fee at requalification.
- Stratified fees - Submission fee, assessment fee, retention fees
- Prequalification fee coupled with requalification and retention fees.

UNFPA fees will be categorised as:

- Assessment fee to be paid at the time of application for prequalification and requalification
 - assessment of quality part
 - assessment of clinical part
- Annual retention fee
- Change fee (to be introduced at a later stage)

All applications will be subjected to the following fees.

Type of fee	Amount (USD)
Annual retention fee	\$9,318
Assessment fee	\$2,761
Total	\$12,079

Frequency and applicability of fees:

Fees	Frequency	Applicability
Annual retention fee	Every year to be paid by 31st January	Male condom - paid for each manufacturing site listed Female condom - per product IUDs - per product

Assessment Fee	At the time of submission for prequalification or requalification	Male condom - paid for each manufacturing site listed Female condom - per product IUDs - per product
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8 Implementation of fees

The fees will be charged effective 01 January 2019. All manufacturers will be expected to pay the fees as per the stage of application. Banking details will be shared with manufacturers by end of December 2018.

Manufacturers and products whose retention fees are not paid by end of June each year will be delisted.

9 Monitoring and evaluation

The fee structure will be monitored and evaluated regularly in line with UNFPA results based programming. These will include

- Assessment of utilisation of funds
- assess the efficiency of the programme
- identify value for money for the programme
- identify areas of improvement

**<http://apps.who.int/medicinedocs/documents/s20307en/s20307en.pdf>