



## Frequently asked questions on WHO/UNFPA Prequalification of Condoms and IUDs Fees

Updated 3 September 2019

### **Q1. Why do manufacturers have to pay the fees?**

The WHO/UNFPA Prequalification 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 reliable source for procurement of contraceptive devices. From 2019 there will be a funding gap for human resources as UNFPA Supplies will no longer fund human resources for prequalification programme. Therefore, it is important that manufacturers contribute to the running of programme in fee modality which will cover the human resources cost.

There are various fee structures for similar programmes. The WHO Prequalification of vaccines is fully financed through manufacturers fees and the other WHO prequalification programmes are partly funded through donations and manufacturers fees.

### **Q2. How much is the fee?**

There are two components in the fee structure; **Retention fee of \$9,318** and **Assessment fee of \$2,761**. Prequalified manufacturers are required to pay the Retention fee annually to maintain listed in UNFPA's published list of prequalified manufacturers. The Assessment fee is to be paid by manufacturer only in the year that manufacturer is due to a reassessment (every 3 years) or upon submission of a new application for prequalification.

### **Q3. What time period does the fee cover?**

The Retention fee is to be paid annually, covering 1 calendar year, 1 January - 31 December. The Assessment fee is to be paid upon submission of an application for requalification or a new application, covering the whole process of assessment.

### **Q4. When is the deadline to pay the fee?**

Ideally, the fee is to be invoiced in January of every year. However, due to a delay in internal process, the 2019 fee was invoiced in August. The delay in invoicing does not affect the time coverage; therefore, 2019 retention fee covers from 1 January to 31 December 2019. The next billing is expected to be in January 2020. Due date of the fee payment is 30 days after the date on the invoice.

### **Q5. Who is responsible for local government's tax, if applicable?**

UNFPA can provide a Tax Exemption letter to the manufacturer, upon request. Should there be any other applicable tax that is not exempted by the local government, manufacturers are kindly asked to cover such tax and to ensure UNFPA receives the full amount of fees. This is to ensure that UNFPA can maintain the programme with funding consistency which is the main objective of the fee structure implementation.

**Q6. If the company is already in the process of prequalification in 2019, how much is the fee?**

The fee structure is implemented in 2019. Retention fee is applied to all prequalified manufacturers listed in 2019. Assessment fee is applied to only manufacturers that are in the process of prequalification in 2019, regardless of stage of the prequalification process that the manufacturer is at.

**Q7. If the site or the product does not obtain a prequalification status after an inspection, does the manufacturer have to pay for assessment fee?**

Yes, if there is any assessment activity conducted in 2019, the manufacturer is required to pay the Assessment fee.

Since non-prequalified manufacturing sites or products will not be listed in UNFPA's published list, the Retention fee is not applied.

**Q8. If a prequalified site will discontinue production, what fees are applied?**

If there is any assessment activity conducted on the site in 2019, the manufacturer is required to pay the **Assessment fee**. Since the non-production site will be delisted from UNFPA's published list of prequalified manufacturing site, the Retention fee is not applied.

**Q9. Is the Assessment fee inclusive of the 3rd party product testing sampled during the inspection?**

Yes. The assessment fee is a flat rate and covers all activities of assessment.

**Q10. If a manufacturer has a main site in one country or region and the testing lab in a different country or region, would this increase the Assessment fee?**

No. The assessment fee is a flat rate and covers all activities of assessment.

**Q11. If a manufacturer has 2 prequalified sites, how much is the retention fee?**

Each site requires a separate assessment and if prequalified, will be listed as separate sites; therefore, the fees will be applied to each site.

**Q12. If a manufacturer produces 2 products at one site, how much is the assessment fee and retention fee?**

Each product requires a separate assessment. While the site inspections can be combined into one extended-period inspection, the inspections will be conducted as separate, as same as the prequalification status of the products. Therefore, the fees will be applied to each product.

**Q13. If a manufacturer split a production of one product to two sites, how much is the assessment fee and retention fee?**

Each product requires one application for reassessment. The manufacturer is required to pay the fees for one product.

**Q14. Not all prequalified manufacturers are supplying products to UNFPA - will the annual fee be discriminatory?**

The WHO/UNFPA Prequalification programme is a separate programme from and independent of UNFPA procurement. The fees are required by all WHO/UNFPA prequalified manufacturers, irrespective of the business that the manufacturer has with UNFPA.

**Q15. Can the fee be reduced for a small manufacturer with low volume of production?**

At the moment, the fee rates are standard to all manufacturers, as the implementation of stratified fees will be challenging. If there is a strong opinion on this, it would be acceptable if any manufacturer(s) share a proposal/draft on how to implement the stratified fee structure and this may be considered at the next cycle of review.

**Q16. Can the fees be divided into monthly payment throughout the year?**

To ensure UNFPA secure funding to maintain the prequalification programme's activities, the fee is to be paid in a lump sum.

**Q17. For manufacturers who have established an LTA with UNFPA with fixed price, can the price be revised to cover the cost of the prequalification fees?**

The WHO/UNFPA Prequalification programme is a separate programme from and independent of UNFPA procurement.

For manufacturers that have LTAs with UNFPA, their agreements are handled by the contracting team, separate from prequalification team. The change in price, if placed, should be brought up with the contracting focal point for consideration. The request will be dealt with as per their policies and procedures.

**Q18. Is it possible to reduce the number of inspections, or extend the re-inspection/ requalification period, or reduce the pre-shipment testing, or to combine audits with other bodies, to reduce the cost of prequalification?**

Prequalification and QA programmes are different. A risk assessment is currently being undertaken for the prequalification programme and looking into the cycle of the requalification period. For the QA there is a risk-based approach to condom quality management which will reduce the amount of pre-shipment testing being done, as well as lead times and costs.

**Q19. Can skip-lot testing or extending the prequalification period be used as a way to reduce the costs?**

The mandatory lot by lot testing is done as part of QA at pre-shipment, which is a quality monitoring activity and is different from the prequalification process which is quasi-regulatory. At prequalification stage, currently the data generated from the prequalification programme is not being tracked and a trend analysis will be done to determine whether it adds value, then reducing the number of batches tested will be taken into consideration.

UNFPA has considered reviewing the cycle of prequalification; taken from a risk-based approach and varies with manufacturer performance. Currently, we are accumulating data to support an extension or reduction of inspection cycle.

**Q20. There is a medical device single audit programme that involves USFDA, TGA, Health Canada, Japan and Brazil; is it possible for UNFPA to join the same programme?**

UNFPA represents all the Member States, while the list consists of 5 Member States and may not be acceptable or easily transferable to the other Member States. We will consider working with the other regulators like WHO does.