

WHO's prequalification assessment fees for medical devices



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1. Introduction

This document has been prepared by the World Health Organization (WHO) to provide manufacturers with information on the fees associated with WHO's prequalification assessment for medical devices (a "product").

There are three types of fees associated with WHO's prequalification assessment process:

1. a prequalification assessment fee per product;
2. a change assessment fee per product; and
3. an annual fee per product.

These fees are non-refundable, and cover part of the cost incurred by WHO in connection with WHO's prequalification process.

The payment of any prequalification fees does not mean or imply any decision by WHO (whether positive or negative) on whether or not a product:

- will be accepted for WHO's prequalification assessment; or
- will be granted WHO prequalification listing; or
- will retain its prequalification listing status for any minimum duration.

2. WHO's prequalification assessment fee per product

A prequalification assessment fee is charged to, and payable by, the manufacturer once its application has been accepted by WHO—i.e., assuming that WHO determines that the product is eligible for WHO's prequalification assessment as described in the *"WHO's prequalification procedure for medical devices" document PQDx_464 (hereinafter, the "PQ Procedure for medical devices")*.

2.1. Payment of fees

WHO will issue an invoice to the manufacturer to request payment of the applicable prequalification assessment fee. The manufacturer must pay the prequalification assessment fee as follows:

- fully in one instalment;
- by wire transfer of funds to WHO's bank account to be designated by WHO in writing as part of the invoice; and
- within 30 days from the date of WHO's invoice (unless another deadline communicated by WHO in the invoice).

The manufacturer must ensure that the prequalification assessment fee has been timely and fully paid, and must submit to WHO the electronic copies of proof of payment with the product dossier in accordance with WHO's instructions for uploading written proof of payment. WHO's prequalification assessment and/or any activities relating thereto will not commence or proceed, unless and until (among other things, see Section 6.3 of the PQ Procedure for medical devices) the prequalification assessment fee has been fully paid by the manufacturer.

If the manufacturer fails to timely and fully pay the prequalification assessment fee, then the application will be terminated, and the product will not undergo WHO's prequalification assessment or be prequalified.

3. Change assessment fee per product

Assuming the product is included in WHO's list of prequalified medical devices, the manufacturer must promptly report to WHO in writing any post-prequalification changes (such as modifications to components, to manufacturing processes and/or to quality management systems).

Based on the change documentation submitted by the manufacturer to WHO, and on the type and level of assessment required in light of the post-prequalification change(s), WHO will determine in its discretion whether a change assessment fee applies.

WHO will issue an invoice to the manufacturer to request payment of the change assessment fee. The manufacturer must pay the change assessment fee as follows:

- fully in one instalment;
- by wire transfer of funds to WHO's bank account to be designated by WHO in writing as part of the invoice; and
- within 30 days from the date of WHO's invoice (unless another deadline is communicated by WHO in the invoice).

The manufacturer must ensure that all applicable change assessment fees have been timely and fully paid and must submit to WHO the electronic copies of proof of payment in accordance with WHO's instructions for uploading written proof of payment. The change assessment and/or any activities relating thereto will not commence or proceed, unless and until the change assessment fee has been fully and timely paid by the manufacturer.

Failure to fully and timely pay the change assessment fees will result in WHO's rejection of the change request. In addition, the validity of the product's prequalification status is subject to and dependent upon the manufacturer's fulfilment, within the applicable deadlines, of all post-qualification obligations and requirements described in Section 11 of the PQ Procedure for medical devices. Failure or delay complying with all post-qualification obligations and requirements will result in the suspension or delisting of the product from WHO's list of prequalified medical devices, as determined by WHO pursuant to and in accordance with the PQ Procedure for medical devices.

4. Annual fee per product

An annual fee is levied for each product listed on WHO's list of prequalified in vitro diagnostics that, as of 1 September of any given year, has been listed on WHO's list of prequalified in vitro diagnostics for 12 months or more.

WHO will issue an invoice to the manufacturer to request payment of the annual fee for the applicable year. The manufacturer must pay the annual fee as follows:

- fully in one instalment;

- by wire transfer of funds to WHO's bank account to be designated by WHO in writing as part of the invoice; and
- before 30 November of the calendar year in which the invoice is issued, unless another deadline is stated in WHO's invoice.

The manufacturer must ensure that all applicable annual fees have been fully and timely paid and must submit to WHO the electronic copies of proof of payment in accordance with WHO's instructions for uploading written proof of payment before 31 December of the calendar year in which the invoice is issued.

Failure to fully and timely pay the annual fee(s) will result in the suspension or delisting of the product from WHO's list of prequalified medical devices, as determined by WHO in its discretion pursuant to and in accordance with the PQ Procedure for medical devices, including Section 11 thereof.

Payment of the annual fee does not, however, mean or imply that the prequalified product will not, for other reasons, be removed or suspended from WHO's list of prequalified medical devices pursuant to and in accordance with the terms of the PQ Procedure for medical devices.

5. Date of effect

This fees, terms and conditions of this document apply with immediate effect.

6. Contact information

Any inquiries regarding WHO's prequalification assessment of medical devices should be addressed to: diagnostics@who.int