WHO’s prequalification assessment fees

WHO’s prequalification assessment of in vitro diagnostics

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1. Introduction

This document (PQDx_299 version 3) has been prepared by the World Health Organization (WHO) to provide manufacturers with information on the fees associated with WHO's prequalification assessment for in vitro diagnostic medical devices (an "IVD" or "product"), and their payment. This document supersedes *"Prequalification fees - Prequalification of In Vitro Diagnostics. Version 2 Geneva: World Health Organization; 2018"*.

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.

For the avoidance of doubt, the fees associated with WHO's prequalification assessment process are separate and distinct from any fees, costs and expenses payable in connection with WHO's performance evaluation procedure. For more information about the latter, please refer to document PQDx_462 "*WHO's Performance evaluation fees".*

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 *"Overview of WHO's prequalification procedure for in vitro diagnostics"* document PQDx_007 (hereinafter, the "PQ Procedure").

If an application is accepted for WHO's prequalification assessment, then the following fee applies:

- for products undergoing a full prequalification assessment, as determined by WHO: US$ 17 000 per product[1]; or
- for products undergoing an abridged prequalification assessment, as determined by WHO: US$ 8 000 per product.

[1] An application may only pertain to one product but may include several product configurations.

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 6.4 of the PQ Procedure) 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 IVDs, 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.

If WHO determines that a change assessment fee applies, the amount of that fee is US$ 3 000 per change request.

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 12 of the PQ Procedure. Failure or delay to comply with all post-qualification obligations and requirements will result in the suspension or delisting of the product from WHO's list of prequalified IVDs, as determined by WHO pursuant to and in accordance with the PQ Procedure.

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.

If WHO determines that an annual fee applies, then the amount of the annual fee is US $4 000 per product.

WHO will issue an invoice to the manufacturer on or before 1 October of each applicable year to request payment of the annual fee. 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 IVDs, as determined by WHO in its discretion pursuant to and in accordance with the PQ Procedure, including Section 12 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 IVDs pursuant to and in accordance with the terms of the PQ Procedure.

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 IVDs should be addressed to: diagnostics@who.int