PREQUALIFICATION ASSESSMENT AND CHANGES ASSESSMENT FEES

WHO Prequalification of In Vitro Diagnostics
1. Introduction

WHO Prequalification of IVDs is a comprehensive quality assessment of individual IVDs through a standardized procedures aimed at determining if the product meets WHO prequalification requirements. In addition, once the product is prequalified, WHO assesses all reportable changes to determine whether the product continues to meet WHO prequalification requirements.

This document provides information on the fees levied for each type of assessment and their payment process.

WHO levies a non-refundable fee on all prequalification applications and change applications to cover in part the cost incurred by the assessment process. There is a fee associated with each type of assessment: (i) prequalification assessment fees apply to prequalification assessment applications, and (ii) change assessment fees apply to certain change assessment applications. The section 4.1 “Exemption from fees” provides details of the categories which are exempt from change assessment fees.

Manufacturers should note that WHO reserves the right to decide, based on the prequalification assessment and change assessment findings, whether a product meets the requirements to become prequalified or whether to accept a change. Payment of the prequalification assessment fees and change assessment fees does not guarantee that the product will be prequalified or that the change will be accepted.

2. Intended audience

This document has been prepared to provide manufacturers with detailed information on the fees applied for prequalification assessments and changes assessments, and their payment process.

3. Prequalification assessment fee and payment process

The prequalification assessment fee is charged to and payable by a manufacturer once its application has been determined as eligible for WHO prequalification assessment.

The prequalification fee will contribute to the costs associated with the product dossier screening and review, performance evaluation commissioned by WHO, manufacturing site(s) inspection, review of labelling and dissemination of prequalification information. Prequalification fees apply equally to performance evaluation options 1 and 2.

The following fees apply to applications selected for prequalification assessment:\1:\n
\1 The fee equally applies to performance evaluation options 1 and 2.
• For applications undergoing a full prequalification assessment: US$ 12 000 per application², including US$ 4 000 for product dossier screening and US$ 8 000 for assessment; or
• For applications undergoing an abridged prequalification assessment: US$ 12 000 per application.

WHO will issue an invoice to the manufacturer to request payment of the prequalification fees. The prequalification process will not commence unless the manufacturer, among other things, pays the prequalification fees described above and provides WHO with an electronic copy of the evidence of payment. Failure to pay the prequalification assessment fee within the defined timelines will result in cancellation of the application.

Payment of the prequalification assessment fee does not guarantee that the product will be prequalified.

4. Change assessment fee and payment process

WHO will review the change documentation³ submitted by the manufacturer to determine the type and level of assessment required. The type and level of the assessment required determines whether change assessment fees are charged. When applicable, the change assessment fee is US$ 3 000 paid in one instalment.

The change assessment fee will contribute to the costs associated with change assessment, and dissemination of change information.

WHO will issue an invoice to the manufacturer to request payment of the change assessment fee. The change assessment process will not commence unless the manufacturer, among other things, pays the full change assessment fee and provides WHO with a hard copy evidence of payment. Failure to pay the change assessment fee within the defined timelines will result in cancellation of the change request application.

Payment of the change assessment fee does not guarantee that the change will be accepted.

4.1 Exemption from change assessment fees
Exemption from change assessment fee is applicable in certain cases. WHO does not charge fees for the assessment of administrative changes⁴ and for certain abridged change reviews. The applicability of the exemption is determined by WHO, in its discretion and on a case by case basis, depending on the extent of the required assessment work. The manufacturer will be informed in writing if such exemption is applicable.

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² Only one product can be submitted within an application. This may include several product configurations.
³ Completed WHO document PQDx 119 Change Report Form and supporting documentation.
⁴ For details on administrative changes refer to WHO document PQDx_121 v2 “Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device”.
5. **Date of effect**

This fees schedule applies to all applications for prequalification assessment and applications for change assessment to a prequalified IVD received on and after 1 August 2017.

6. **Contact information**

Any inquiries regarding WHO Prequalification of IVDs should be addressed to: [diagnostics@who.int](mailto:diagnostics@who.int)