PREQUALIFICATION FEES FOR MALE CIRCUMCISION DEVICES

WHO Prequalification of Male Circumcision Devices

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1. Introduction

WHO Prequalification of Male Circumcision Devices undertakes a comprehensive assessment of individual male circumcision devices (MCDs) through a standardized procedure aimed at determining if the product meets WHO prequalification requirements. In addition, once a product is prequalified, WHO assesses all reportable changes to verify that the product continues to meet WHO prequalification requirements.

This document provides information on the fees associated with WHO prequalification of MCDs, and the payment process thereof. There are three types of fees associated with WHO prequalification:

- A prequalification assessment fee per product;
- An annual fee per product; and
- A change assessment fee per product.

The abovementioned prequalification assessment, annual and change assessment fees are non-refundable, and cover in part the cost incurred by WHO in connection with the prequalification process.

Manufacturers should note that WHO reserves the right to decide, based on the prequalification assessment and change assessment findings, whether a product meets the applicable WHO requirements to be prequalified and/or whether to accept a change.

Payment of the prequalification assessment, the annual and/or the change assessment fees does not guarantee that the product will be prequalified, or that a prequalified product will maintain its WHO-prequalified status, or that the change will be accepted.

The section "Exemption from fees" provides details of the categories of changes which are exempt from change fees.

2. Intended audience

This document has been prepared to provide manufacturers with detailed information on the fees applicable to WHO prequalification of MCDs and the payment process thereof.

3. Prequalification assessment fee per product and payment process

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

The prequalification assessment fee will contribute to cover part of the costs associated with product dossier screening, product dossier review, manufacturing site(s) inspection, review of labelling and dissemination of prequalification information.

The following fees apply to applications accepted for WHO prequalification of MCDs assessment:

- For applications undergoing a prequalification assessment: US$ 5 000 for dossier screening and US$ 12 000 for product assessment, per product[1].

WHO will issue an invoice to the manufacturer to request payment of the prequalification assessment fee. The prequalification assessment process will not commence unless WHO has first received the full amount of the applicable prequalification assessment fee as well as written evidence of payment thereof. 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, however, guarantee that the product will be prequalified by WHO.

4. Change assessment fee per product and payment process

WHO will review the change documentation[2] submitted by the manufacturer to determine the type and level of assessment required which, in turn, will determine 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 cover the costs associated with the change assessment and dissemination of the 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 WHO has first received the full amount of the change assessment fee as well as written evidence of the payment thereof. 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, however, guarantee that the product will be prequalified or the change accepted by WHO.

4.1 Exemption of change assessment fees