World Health Organization

# OVERVIEW OF THE WHO PREQUALIFICATION OF MALE CIRCUMCISION DEVICES ASSESSMENT

*WHO Prequalification of Male Circumcision Devices*

WHO/MVA/EMP/RHT/PQT/2019.02 version 2



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## 1. Introduction

World Health Organization (WHO) prequalification of male circumcision devices (MCDs) is coordinated through the department of Essential Medicines and Health Products. Focus is placed on Male Circumcision Devices for their potential to accelerate delivery of male circumcision programmes in high HIV incidence settings and, thereby, contribute to reducing the risk of HIV infection in adult male populations.

WHO prequalification of Male Circumcision Devices is a comprehensive quality assessment of individual MCDs through a standardized procedure aimed at determining whether the product meets WHO prequalification requirements.

The prequalification assessment process for MCDs includes the following components:

- review of the application form;
- review of the product dossier, including review of clinical evidence;
- inspection of the manufacturing site(s); and
- labelling review.

Products submitted for prequalification assessment that meet, as determined by WHO, the WHO prequalification requirements are included in the WHO list of prequalified MCDs. The duration of the validity of the prequalification status of a product is dependent on the manufacturer's fulfilment, within the applicable deadlines, of its post-qualification obligations and requirements, including:

- prequalification commitments;
- annual reporting;
- reporting of changes;
- post-market surveillance obligations;
- receiving re-inspections; and
- ongoing compliance with WHO prequalification technical specifications, as applicable.

The findings of WHO prequalification[1] are used to assess the safety, quality and performance of commercially available MCDs for the purpose of providing guidance to interested United Nations (UN) agencies and WHO Member States in their procurement decisions.

## 2. Intended audience

This document has been prepared to provide manufacturers with an overview of the WHO process for prequalification assessment of MCDs (the prequalification assessment process). Manufacturers wishing to apply for WHO prequalification of their product(s) should read this document before applying, so that they can be aware of and prepared for all stages of the prequalification assessment process.

[1] Prequalification does not imply any approval by WHO of the product and manufacturing site(s). Moreover, prequalification does not constitute any endorsement or warranty by WHO of the fitness of any product for a particular purpose, including its safety, quality or performance.

## 3. Definitions

| | |
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| Dossier screening | Systematic process to ensure that all requisite sections of the product dossier are submitted |
| Dossier review | Review and assessment of documentation including data, protocols, reports, procedures, etc., to support the quality, safety and performance of a product for the purpose of WHO prequalification. |
| Inspection of manufacturing site(s) | Inspection of the manufacturing site(s) of product undergoing prequalification assessment |
| Labelling review | Review and assessment of the instructions for use and product labels |
| Manufacturer | Any natural or legal person with responsibility for design and/or manufacture of an MCD with the intention of making the MCD available for use, under his or her name, whether or not such an MCD is designed and/or manufactured by that person him- or herself or on his or her behalf by (an)other person(s). |
| Rebranded product | A rebranded product is identical in every respect to the product manufactured by the original manufacturer, except that the product is labelled with the "rebranded" product name and product code, and bears the rebrander's name. |
| Rebrander | A manufacturer of a rebranded MCD. |
| Regulatory version | Relates to the information associated with a submission for approval by a regulatory authority. The submitted version is defined by all of the documentation related to development, manufacture and intended use, labelling and post-market surveillance of the product and all the documented evidence supporting the safety and performance claims associated with that submission. If any aspect of this documentation differs in any way between the submissions to different regulatory authorities or assessment bodies (United States Food and Drug Administration, Health Canada, a Notified Body for CE marking, etc.) it is considered to be a different regulatory version. |

## 4. Abbreviations

| | |
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| GHTF | Global Harmonization Task Force |
| IMDRF | International Medical Device Regulators Forum |
| IFU | instructions for use |
| ISO | International Organization for Standardization |
| MCD | male circumcision device |

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| NRA | national regulatory authority |
| SOP | standard operating procedure |
| UN | United Nations |
| WHO | World Health Organization |

## 5. About prequalification of MCDs and procurement

The goal of the WHO prequalification of MCDs is to assess the safety, quality and performance of commercially available MCDs for the purpose of providing guidance to interested UN agencies, WHO Member States in their procurement decisions.

Once a product has been prequalified, it is included in the WHO list of prequalified MCDs and becomes eligible to participate in the procurement processes of UN agencies. WHO Member States are encouraged to use the WHO list of prequalified MCDs for their respective procurement decisions. Nevertheless, UN agencies and WHO Member States using information from the WHO prequalification of MCDs process should perform additional steps of qualification prior to purchasing products included in this list including steps such as ensuring the supplier's financing stability and standing, the ability to supply the required quantities of the product, security of the supply chain, quality control testing, and other relevant aspects.

## 6. Eligibility for prequalification of MCDs

### 6.1. Original manufacturer

Applications for WHO prequalification of MCDs are accepted only from the legal manufacturer of the product.[2]

### 6.2. Rebranded products

WHO is aware that several manufacturers purchase finalized products from other companies, and then "rebrand" and place these products on the market under their own name or brand. Such products are also known as original equipment manufacturer (OEM) products.

WHO considers a rebranded product to be one that is manufactured under identical conditions at the same manufacturing site(s) as the original product. In other words, a rebranded product is identical in every respect (including the intended use) to the product manufactured by the original manufacturer, except that the product is labelled with the rebranded product name and product code, and bears the rebrander's name or brand.

Rebranded products are outside the scope of the WHO prequalification of MCDs process, and hence are not accepted for prequalification assessment.

[2] The definition of a manufacturer is based on the definition used by the Global Harmonization Task Force (GHTF), and later adopted by International Medical Device Regulators Forum (IMDRF). This internationally accepted approach has been adopted to ensure that there is a clear understanding of the term "manufacturer" across international markets. For further details see: http://www.imdrf.org/

### 6.3. Commercial availability

Applications for WHO prequalification of MCDs are only accepted for products that are commercially available at the time of submission for prequalification assessment.

### 6.4. Eligibility principles and eligibility criteria

To meet the needs of WHO Member States and UN agencies, the prequalification scope is defined according to the following prequalification eligibility principles:

- need for male circumcision devices for adult male populations ;
- appropriateness of the product for use in resource-limited settings;
- requests from WHO Member States for particular male circumcision devices;
- recommendation in WHO guidelines;
- the performance capabilities of particular male circumcision devices; and/or
- the availability of currently prequalified products that are similar or the same.

The eligibility criteria are periodically reviewed by WHO, in consultation with other UN agencies and relevant experts, and made publicly available by WHO on its website. WHO also obtains input from WHO Member States to determine which male circumcision devices are of priority to them.

## 7. Applying for WHO prequalification

To ensure that WHO can prequalify MCDs as efficiently as possible, manufacturers should be fully prepared for the prequalification assessment process when they apply for WHO prequalification. Manufacturers may wish to contact the WHO Prequalification Team – Male Circumcision Devices Assessment (email: diagnostics@who.int) and/or the WHO Prequalification Team – Inspections services (email: prequalinspection@who.int) to commence discussions on the prequalification assessment processes and requirements before applying. In addition, the WHO Prequalification webpage provides guidance materials to assist manufacturers in ensuring their readiness for WHO prequalification.[3]

The manufacturer must complete an application form (WHO document PQMC_015 *Application form)* and must provide WHO with all requested supporting documentation in accordance with the WHO document PQMC_017 *Instructions for the completion of the application form*.

The application form and the requisite attachments (authorization letter and instructions for use) must be submitted, preferably electronically, by the manufacturer to WHO for review. A completed application form provides summary information about the product, its regulatory version and the manufacturer. The details provided in this form will inform WHO in its decision on whether or not the product submitted is eligible for prequalification assessment. It is also used to determine the regulatory version intended for prequalification and to plan for each of the components of the prequalification assessment process. It is therefore important for the manufacturer to ensure that the information supplied in the application form is accurate and complete.

The prequalification applicationform and supporting documentation will be reviewed by WHO against the established eligibility criteria to determine the product's eligibility for prequalification assessment. If necessary, the manufacturer may receive a communication from WHO requesting additional information and/or clarifications to assist it in the eligibility decision. The manufacturer

[3] https://www.who.int/diagnostics_laboratory/evaluations/prequalification_male_circumcision_devices/en/

must provide WHO with the information and/or clarifications so requested within the deadlines prescribed by WHO. WHO will inform the manufacturer in writing of WHO's decision concerning whether or not the product is eligible for prequalification assessment.

If a product is found to be eligible for prequalification assessment, WHO will request the manufacturer to complete, sign and return to WHO the Letter of Agreement, which will serve: (i) as an agreement between WHO and the manufacturer on the participation of the product in the prequalification assessment process, and (ii) as the manufacturer's acceptance of, and commitment to comply with, the provisions of the prequalification assessment process. A prequalification dossier screening and assessment fee will also be payable by the manufacturer.

Before the prequalification assessment of a product that has been found eligible by WHO may commence, the manufacturer must deliver to WHO: (i) a signed and completed Letter of Agreement, and (ii) proof of payment the the applicable prequalification fee.

## 8. Prequalification assessment

### 8.1. Prequalification assessment process

The WHO prequalification assessment process for MCDs consists of the following components (see Figure 1):

- review of a product dossier, including review of clinical evidence;
- inspection of manufacturing site(s); and
- labelling review.