Eligibility criteria for WHO's prequalification assessment of in vitro diagnostics

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ISBN 978-92-4-011804-1 (electronic version)
ISBN 978-92-4-011805-8 (print version)

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1. Introduction

This document has been prepared by the World Health Organization (WHO) to provide information on the eligibility principles and eligibility criteria applicable for an in vitro diagnostic medical device (each, an "IVD" or "product") to undergo WHO's prequalification assessment pursuant to document PQDx_007 *"Overview of WHO's prequalification procedure for in vitro diagnostics"* (hereinafter, the "PQ Procedure"). This document supersedes *"Eligibility criteria for WHO prequalification of in vitro diagnostics, Prequalification of in vitro diagnostics, March 2025 update".*

To be eligible to apply for and undergo WHO's prequalification assessment, the relevant product must, among other things, meet the eligibility principles and eligibility criteria established by WHO, as further described in this document. Manufacturers wishing to apply for WHO's prequalification assessment of their product(s) should read this document before doing so.

This document excludes medical devices that are not IVDs.

2. Eligibility for WHO's prequalification assessment of IVDs

2.1. Eligibility principles

To facilitate meeting the needs of WHO Member States and UN agencies, the scope of WHO's prequalification assessment is defined by WHO according to the following eligibility principles:

- The need for IVDs for a particular disease or disease state; and
- The appropriateness of the product for use in resource-limited settings; and
- The requests from WHO Member States for particular IVDs; and
- The products of interest to UN organizations and other procurement agencies; and
- The existing or planned recommendation in WHO disease specific testing guidelines.

Applications for WHO's prequalification assessment of IVDs are accepted only for products that are found by WHO to meet the eligibility principles set forth in this document.

2.2. Eligibility criteria

Applications for WHO's prequalification assessment of IVDs are only accepted for products that are found by WHO to meet the below eligibility criteria:[1]

- the Expression of Interest for WHO's performance evaluation of that IVD must have been submitted to and accepted by WHO (where applicable)—see also Section 2.2.1 below; and
- the product must be manufactured, and the application must be submitted, by the original manufacturer of the product (i.e., applications from a rebrander are not accepted)—see also Section 2.2.2 below; and

[1] WHO reserves the right to apply other criteria dependent on changing global health needs, the particular needs of WHO Member States, and the emergence of new and relevant technologies.

- the product must be in design lock-down when the application for WHO's prequalification assessment is submitted by the manufacturer to WHO—see also Section 2.2.3 below; and
- the product must have been validated by the manufacturer and the established performance claims must be included in the IFU.

In addition, WHO reserves the right to determine eligibility for WHO's prequalification assessment of an IVD considering the product categories for which there exist few other prequalified products[2].

The eligibility criteria may be reviewed and amended by WHO, following internal consultation with WHO programmes.

2.2.1. Submission and acceptance of an Expression of Interest for WHO's performance evaluation

WHO's performance evaluation of an IVD is a prerequisite for certain IVDs, as described in Section 3 of this document, to be submitted to and apply for WHO's prequalification assessment.

Before a manufacturer may apply for WHO's prequalification assessment of an IVD, an Expression of Interest for WHO's performance evaluation of that IVD must have first been duly completed and submitted by the manufacturer to, and accepted by, WHO in accordance with the provisions set forth in document PQDx_458 *"WHO's performance evaluation procedure for in vitro diagnostics"*.

Without prejudice to the other requirements set forth in the PQ Procedure, an application for WHO's prequalification assessment of an IVD will not be accepted by WHO unless and until, among other things, a complete Expression of Interest for WHO's performance evaluation of that IVD has first been received and accepted by WHO.

For the avoidance of doubt, WHO's performance evaluation of IVDs and its procedure are separate from WHO's prequalification assessment of IVDs and the PQ Procedure. In this respect, WHO's performance evaluation is a prerequisite to, rather than a component of, WHO's prequalification assessment of IVDs. The fact that an IVD has been accepted for, is undergoing and/or has completed a WHO's performance evaluation does not mean or imply that such IVD will be accepted for WHO's prequalification assessment and/or be granted WHO's prequalification listing.

2.2.2. Original manufacturer

Applications for WHO's prequalification assessment of IVDs may only be submitted by the original manufacturer of the product.[3] WHO will not accept applications submitted by rebranders or applications of rebranded products.

[2] This document only applies to IVD medical devices. The eligibility criteria for WHO's prequalification assessment of male circumcision devices are defined in a separate document.

[3] The definitions of a "manufacturer", "rebrander" and "rebranded product" are found in document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics".*

2.2.3. Design lock-down

Without prejudice to the other eligibility criteria, applications for WHO's prequalification assessment of IVDs are only accepted for products that have final design lock down at the time such application is submitted to WHO. [4] Any exemptions must be agreed upon by WHO in writing prior to the submission of the application for prequalification.

3. Lists of IVDs eligible for WHO's prequalification assessment

Subject to the terms and conditions of the PQ Procedure and to the aforementioned eligibility principles and eligibility criteria, WHO currently accepts for WHO's prequalification assessment the types of IVDs that are listed in Table 1 and Table 2 on WHO's website.

Table 1 (available at https://extranet.who.int/prequal/vitro-diagnostics/vitro-diagnostics-eligible-who-prequalification) sets forth the types of IVDs that are eligible for WHO's prequalification assessment and for which WHO's performance evaluation *is* required as a prerequisite for that IVD to apply for WHO's prequalification assessment.

Table 2 (available at https://extranet.who.int/prequal/vitro-diagnostics/vitro-diagnostics-eligible-who-prequalification) sets forth the types of IVDs that are eligible for WHO's prequalification assessment and for which WHO's performance evaluation is currently *not* required before the manufacturer may apply for WHO's prequalification assessment of that product.

WHO reserves the right to review and amend, from time to time, Table 1 and/or Table 2 and the IVDs listed therein.

4. Assessment of eligibility and communication of outcome

Once the manufacturer has submitted to WHO the complete pre-submission form and required attachments, WHO will review them against the aforementioned eligibility principles and criteria. Thereafter, WHO will determine and inform the manufacturer in writing:

- whether or not the application is accepted (i.e., whether or not product is eligible for WHO's prequalification assessment); and
- assuming the application is accepted, the next steps to be followed depending on the prequalification assessment pathway (full or abridged) applicable to the product.

If the application is accepted (i.e., if the product is found by WHO to be eligible for WHO's prequalification assessment), then WHO will also request the manufacturer to, among other things: (a) complete, sign and return to WHO a Letter of Agreement for WHO's prequalification assessment of the product, using the document provided by WHO for this purpose, as well as (b) pay WHO's prequalification fees.

[4] The definition of "design lockdown" is provided in document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics".*

Before WHO's prequalification assessment of a product may commence and proceed, the manufacturer must first ensure that it has fully met the conditions mentioned in clauses (i), (ii) and (iii) of Section 6.4 of the PQ Procedure.

If WHO finds that the product is not eligible for WHO's prequalification assessment, then the application will be rejected, and the product will not be accepted for or undergo WHO's prequalification assessment.

5. Relevant documents

The following WHO documents and webpages, among others, provide information to guide the manufacturer through the requirements of WHO's prequalification assessment:

- https://extranet.who.int/prequal/vitro-diagnostics/prequalification-guidance
- Overview of WHO's prequalification procedure for in vitro diagnostics. Geneva: World Health Organization (PQDx_007)
- Pre-submission form. Geneva: World Health Organization (PQDx_15)
- Instructions for completion of the pre-submission form. Geneva: World Health Organization (PQDx_17)
- https://extranet.who.int/prequal/ivd-performance-evaluation

6. Contact information

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