Eligibility criteria for WHO's performance evaluation of in vitro diagnostics

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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 that apply to in vitro diagnostic medical devices (each, an "IVD" or a "product") that undergo WHO's performance evaluation pursuant to WHO's performance evaluation procedure for in vitro diagnostics (hereinafter, the "PE Procedure").[1]

Effective as of 1 January 2026, WHO's performance evaluation of an IVD pursuant to the PE Procedure is a separate process from (as opposed to a component to), as well as a prerequisite for that product to apply for assessment under, WHO's prequalification procedure for IVDs.

To be eligible to apply for and undergo WHO's performance evaluation under the PE Procedure, the relevant product must, among other things, meet the eligibility principles and eligibility criteria established by WHO, as further described in this document.

This document excludes medical devices that are not IVDs.

2 Intended audience

This document has been prepared to provide an overview of the eligibility principles and eligibility criteria applicable to IVDs submitted for WHO's performance evaluation. Manufacturers wishing to submit an Expression of Interest for WHO's performance evaluation of their product(s) should read this document before doing so.

3 Eligibility principles for WHO's performance evaluation of IVDs

To facilitate meeting the needs of WHO Member States and UN agencies, funds and programmes, the scope of WHO's performance evaluation 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.

Expressions of Interest for WHO's performance evaluation of IVDs are accepted only for products that are found by WHO to meet the eligibility principles set forth in this document.

4 Eligibility criteria for WHO's performance evaluation of IVDs

Expressions of Interest for WHO's performance evaluation of an IVD are only accepted for products that are found by WHO to meet the below eligibility criteria: [2]

- The product must be manufactured, and the Expression of Interest form must be submitted, by the original manufacturer of the product (i.e., Expressions of Interest from a rebrander are not accepted) - see also Section 4.1 below; and

[1] Refer to document PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics".*

[2] 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 Expression of Interest is submitted by the manufacturer to WHO – see also Section 4.2 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 performance evaluation of an IVD considering the product categories for which there exist few other prequalified products.[3]

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

For the avoidance of doubt, WHO's performance evaluation of IVDs and its procedure are separate from WHO's prequalification assessment of IVDs and its procedure.[4] 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.

4.1 Original manufacturer

Expressions of Interest for WHO's performance evaluation of IVDs may only be submitted by the original manufacturer of the product.[5] WHO will not accept Expressions of Interest submitted by rebranders or Expressions of Interest for WHO's performance evaluation of rebranded products.

4.2 Design lock-down

Without prejudice to the other eligibility criteria, Expressions of Interest for WHO's performance evaluation of IVDs are only accepted for products that have final design lock down at the time such Expression of interest is submitted to WHO.[6]
Any exemptions must be agreed to by WHO, in writing, prior to the submission of the Expressions of Interest.

5 IVDs eligible for WHO's performance evaluation of IVDs

Subject to the terms and conditions of the PE Procedure and to the aforementioned eligibility principles and eligibility criteria, WHO currently accepts for WHO's performance evaluation the types of IVDs that are listed on Table 1 *Products currently eligible for WHO's performance evaluation as a prerequisite to apply for WHO's prequalification assessment* on WHO's performance evaluation website https://extranet.who.int/prequal/ivd-performance-evaluation.

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

[3] This document only applies to IVD medical devices. The eligibility principles and criteria applicable to WHO's assessment of male circumcision devices are defined in a separate document.
[4] Refer to document PQDx_007 "*Overview of WHO's prequalification procedure for in vitro diagnostics".*
[5] The definitions of a "manufacturer", "rebrander" and "rebranded product" are found in document PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics".*
[6] The definition of "design lockdown" is provided in document PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics".*

6 IVDs for which WHO's performance evaluation of IVDs is not required

WHO may from time to time determine (in its discretion and taking into account the risk classification of a type of IVDs) that WHO's performance evaluation of a type of product is not required before that product may apply for WHO's prequalification assessment.

Table 2 *Products for which WHO's performance evaluation is not required as a prerequisite to apply for WHO's prequalification assessment* on WHO's performance evaluation website https://extranet.who.int/prequal/ivd-performance-evaluation sets out the types of IVDs for which WHO's performance evaluation is currently not required before the manufacturer may apply for WHO's prequalification assessment of such IVDs.

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

7 Assessment of eligibility and communication of outcome

Once the manufacturer has submitted to WHO the complete Expression of Interest form and supporting documentation, 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 Expression of Interest is accepted (i.e., whether or not product is eligible for WHO's performance evaluation); and
- assuming the Expression of Interest is accepted, (i.e., if the product is found by WHO to be eligible for WHO's performance evaluation), then WHO will request the manufacturer, among other things, to: (a) complete, sign and return to WHO a Letter of Agreement for WHO's performance evaluation of the product, using the document provided by WHO for this purpose; and (b) pay WHO's performance evaluation fees (as such term is defined in the PE Procedure).

Before WHO's performance evaluation of a product may commence and proceed, the manufacturer must first ensure that the conditions mentioned in clauses (i), (ii) and (iii) of Section 7.2 of the PE Procedure have been fully met.

If WHO finds that the product is not eligible for WHO's performance evaluation, then the Expression of Interest will be rejected, and the product will not be accepted for or undergo WHO's performance evaluation.

8 Relevant documents

The following WHO documents provide information to guide the manufacturer through the requirements of WHO's performance evaluation and can be found at https://extranet.who.int/prequal/ivd-performance-evaluation:

- WHO's performance evaluation procedure for in vitro diagnostics. Geneva: World Health Organization; (PQDx_458).
- Expression of Interest form for WHO's performance evaluation of in vitro diagnostics. Geneva: World Health Organization; (PQDx_460).
- Instructions for the completion of the Expression of interest for WHO's performance evaluation of in vitro diagnostics. Geneva: World Health Organization; (PQDx_461).

- WHO's Performance evaluation fees. Geneva: World Health Organization; (PQDx_462).

9 Contact information

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