Instructions for completion of the Expression of Interest form for WHO's performance evaluation of in vitro diagnostics

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A. Introduction

WHO's performance evaluation independently verifies the performance and operational characteristics of an in vitro diagnostic (IVD) medical device, including those that are considered essential for such IVD's use in resource-limited settings. Although WHO's performance evaluation of an IVD is a separate procedure from WHO's prequalification assessment, the former is a prerequisite step for a manufacturer to apply for assessment under WHO's prequalification procedure of IVDs[1].

To apply for WHO's performance evaluation of an IVD, manufacturers are required to complete and submit to WHO an Expression of Interest (EOI) using the form found in document PQDx_460 "*Expression of interest form for WHO's performance evaluation of in vitro diagnostics*", together with the necessary supporting documentation. The Expression of Interest form assists WHO to determine whether or not a product is eligible for WHO's performance evaluation.

This document is intended to assist manufacturers in correctly completing the Expression of Interest form for WHO's performance evaluation of IVDs.

B. Intended audience

Manufacturers who wish to apply for WHO's performance evaluation of their product(s) should read the instructions in this document and the Expression of Interest (EOI) form before completing the EOI form.

In addition, manufacturers should read the document PQDx_458 *"WHO's performance evaluation procedure for in vitro diagnostics"* and document PQDx_459 *"Eligibility criteria for WHO's performance evaluation"* before submitting an EOI form, so that they can be aware of and prepared for all stages of WHO's performance evaluation process.

C. Submitting the expression of interest form

Once the manufacturer has duly and fully completed, signed and dated the EOI form and its attachments (e.g., official letter regarding the manufacturer's authorized contacts; instructions for use of the product, in English), the documents are required to be submitted electronically to diagnostics@who.int. It is required that all documents are submitted as searchable PDF files.

The numbering of the following sections corresponds to and refers to those sections in the EOI form. The manufacturer is requested to not modify the descriptions in the EOI tables.

1. Manufacturer Information

1.1. Legal manufacturer

Please provide all information required under this section about the manufacturer of the IVD product in question.

For the purpose of WHO's performance evaluation, the following definition of "manufacturer" applies[2]:

[1] This requirement applies when WHO's performance evaluation of the product is required per document PQDx_459 *"Eligibility criteria for WHO's performance evaluation of in vitro diagnostics".*

[2] From document PQDx_458 *"WHO's performance evaluation procedure for in vitro diagnostics".*

"Manufacturer" means any natural or legal person with responsibility for design and/or manufacture of an IVD with the intention of making the IVD available for use, under his or her name, whether or not such an IVD is designed and/or manufactured by that person him- or herself or on his or her behalf by (an)other person(s).

EOIs for WHO's performance evaluation are accepted only from the original manufacturer of the product.

1.2. Authorized contacts for the manufacturer

Please insert all the information required under this section regarding each of the two authorized contacts for the manufacturer.

The "authorized contacts for the manufacturer" are two officers, employees or representatives of the manufacturer who are duly and fully authorized and designated by the manufacturer to act in the name and on behalf of the manufacturer in all respects and for all purposes in connection with WHO's performance evaluation of the IVD in question.

These two authorized contacts will be the primary contact points for WHO in relation to WHO's performance evaluation for the IVD for which the EOI form is submitted. Therefore, the manufacturer must ensure that all contact details provided in the EOI form are current, complete and correct.

In connection with this section, the manufacturer must also submit to WHO an official letter, signed by a duly authorized representative of the manufacturer, stating that the persons listed as "authorized contacts" in section 1 of the EOI form (which persons must also be named in that letter) are duly and fully authorized/designated to act in the name and on behalf of the manufacturer in all respects and for all purposes in connection with the WHO's performance evaluation of the product in question (which product must also be identified in that letter). This letter must be sent along with the completed EOI form.

In the event that, at any time during WHO's performance evaluation process, there is a change in the name(s) and/or contact information of any authorized contact(s), the manufacturer must promptly notify WHO, in writing, thereof and of the updated name(s) and contact information of the authorized contacts. Such notice must be given by official letter as described above, sent to WHO by email to diagnostics@who.int.

2. Product – Information

2.1. Product name and product code/catalogue number[3]

2.1.1. Only one IVD is permitted per EOI form. Provide the name for one product only.

2.1.2. Provide the product code(s) or catalogue number(s) for the product.

2.1.3. For each product size/configuration, provide the product code/catalogue number, product kit size, and list the contents, the quantity/volume of all components.

2.1.4. If reagents are supplied in more than one box, provide the name and product code/catalogue number for each box. For example, if controls are provided separately to the test reagents, provide the catalogue number for the controls here.

- For each different box size of reagent, list the number of tests and product code for each

[3] WHO must be notified of all changes made to this product, as per document PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics*."

box size

2.1.5. Provide all information required under this section regarding any instrument required to run the assay.

In this section, a "**dedicated instrumentation**" defines a situation where the assay must be run on a specific instrument as part of the testing protocol. The instrument and assay reagents are only ever used in combination to perform the assay.

2.1.6. Provide the date of design lock-down for the product.

For purposes of WHO's performance evaluation, the term "design lock-down" relates to a formal milestone in the IVD, medical device, or system development lifecycle at which the design is considered finalized: all design inputs have been addressed, and verification and validation activities are complete. The design is placed under configuration control and formally released for manufacturing, regulatory submission, or subsequent development stages. From this point forward, any modifications are strictly managed through a documented design change control process, including risk management review, necessary validation and verification and—where applicable—regulatory notification or approval, in order to maintain a stable and traceable design baseline.
NOTE: EOIs are only accepted for products that have final design lock down at the time of submission for WHO's performance evaluation.

2.2. Current instructions for use and user manual

Attach a copy of the English language version of the instructions for use (package insert). Provide document control details for the instructions for use and the user manual(s) relevant to the product.

The version of the instructions for use submitted with the Expression of Interest form will be considered the official version submitted for WHO's performance evaluation. During the course of WHO's performance evaluation process, the manufacturer cannot make changes to this version of the instructions for use without prior written notice to and agreement from WHO. Any changes to such instructions for use version that was submitted with the Expression of Interest form must be agreed with WHO prior to their implementation or the performance evaluation will be terminated.

2.3. Transport, storage and operating temperatures

2.3.1. The transport, storage and operating temperature ranges for all components must be clearly specified by the manufacturer for the product and individually for reagents which are provided in more than one box. The manufacturer shall provide the shelf life of the product as claimed on the packaging (expiry date), and individually for reagents which are provided in more than one box.

"Shelf-life upon manufacture" is the period of time from when the product is released for supply until the expiry date - during which the product performance is assured by the manufacturer while handled and stored under defined conditions.

2.3.2. Provide details of any other specified storage conditions applicable to the product if applicable.

3. Product – Disease Category, Analyte and Method

For questions in section 3, tick/check the boxes that are relevant to the product.

4. Product – Operation

4.1. Assay controls

Please provide all information required under this section regarding the assay controls that are part of the product or provided separately.

"**Control specimens**" (also called "test-kit controls") refer to preparations that are specifically designed by the manufacturer for this product. These control specimens are usually a positive and a negative control specimen.

4.2. Product usage

Please provide all information required under this section regarding the product usage and throughput.

"**Single run**" refers to the number of specimens that can be tested consecutively by one operator without interruption (unless the recommended operation requires such interruption).

4.3. Indicative cost

Please provide the indicative cost per test in US Dollars and, if applicable, the cost of the dedicated instrumentation required to perform the assay.

5. Product – Performance Characteristics

5.1. Performance characteristics for serology or antigen EIAs and RDTs

Please provide all information required under this section regarding the validated performance characteristics of the product. Section 5.1. applies only to serology or antigen EIAs and RDTs and should be left blank for other types of products.

"**Sensitivity**" refers to clinical or diagnostic sensitivity. "Sensitivity" is the ability of a test to give a positive result for individuals that have the disease or disorder for which they are being tested. The disease status of the individual must be predefined by criteria that are independent of the test under consideration.[4]

"**Specificity**" refers to clinical or diagnostic specificity. "Specificity" is the ability of a test to give a negative result for individuals that do not have the disease or disorder for which they are being tested. The negative disease status of the individual must be predefined by criteria that are independent of the test under consideration.[4]

5.2. Specifications for nucleic acid tests

Please provide all information required under this section regarding the validated performance characteristics of the product. Section 5.2. applies only to nucleic acid tests and should be left blank for other types of products.

6. Regulatory and Commercial status of the Product

6.1. Regulatory status of the product

Please provide all information required under this section regarding the regulatory status of the product being submitted for WHO's performance evaluation. Please identify the regulatory

[4] This definition is based on terminology used in the publicly available "Harmonized Terminology Database" that is compiled by the Clinical and Laboratory Standards Institute. https://htd.clsi.org/

version of the product submitted for WHO's performance evaluation (or planned regulatory version if the product is not yet commercially available).

A **"regulatory version"** relates to all the information and documentation associated with a submission for approval of a product by a regulatory authority including, without limitation, all documentation related to development, manufacture, intended use, labelling and post-market surveillance of the product in question, as well as all documented evidence supporting the safety and performance claims associated with that submission. In the event that (i) regulatory versions of a product have been submitted to different regulatory authorities or assessment bodies (e.g., United States Food and Drug Administration, Health Canada, a Notified Body for CE marking, etc.) and (ii) any aspect of the documentation or information associated with such submitted regulatory versions differs in any way, then the submitted regulatory versions are considered to be a *different* regulatory version.

NOTE: Do not include certification information relating to ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes here. Questions relating to ISO 13485 are addressed in Section 7 of the EOI.

6.2. Commercial agreements and re-branding

Please provide all information required under this section regarding rebranding of the product, or whether the product or any of the major components thereof sourced from another manufacturer. WHO requires that this commercial agreement information be made available to WHO in order to determine whether or not a product is eligible for WHO's performance evaluation. EOIs for WHO performance evaluations are accepted only from the original manufacturer of the product.

6.3. History of product assessment by WHO

Provide information required under this section on any previous WHO assessments of the product.

7. Manufacturer – Quality Management System

An effective quality management system is a key consideration for all manufacturers of IVDs. Therefore, products submitted for WHO's performance evaluation must be manufactured under an appropriate quality management system.

The quality management standard "*ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes"* is considered to be a benchmark in quality management for the manufacturers of diagnostic products by regulatory agencies throughout the world.

Provide all information required under this section about the manufacturer's quality management system and conformity to the referenced standards.

8. Manufacturer – Sites of product manufacture

8.1. Sites of manufacture

Please provide all information required under this section about all sites that are involved in each and every stage of the manufacture of the product, as per the table provided under this section. Please do not modify the description of the table.

8.2. Key suppliers

Please provide all information required under this section about all key suppliers which supply products/components and/or services for the manufacture of the product (e.g. raw materials, enzymes, key components, bulk chemicals and reagents, instruments, etc.).

9. Commissioning of the WHO's performance evaluation

Please choose one of two options for commissioning of WHO's performance evaluation.

WHO's performance evaluation of the product is carried out by laboratory designated by WHO as a performance evaluation laboratory (PEL), as defined in the document PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics".* The list of WHO performance evaluating laboratories is available at: https://extranet.who.int/prequal/vitro-diagnostics/prequalified/performance-evaluation-laboratories. The PEL will be responsible for implementing the performance evaluation of the product subject to and in accordance with PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics"* and using the WHO performance evaluation protocol.

Under this section, the manufacturer must choose one of two options for the commissioning of WHO's performance evaluation:

- **Option A:** Performance evaluation commissioned by the manufacturer and carried out at a PEL selected by the manufacturer.
- **Option B:** Performance evaluation commissioned by WHO and carried out at a PEL selected by WHO.

The fees, costs and expenses arising from or relating to any activities required for WHO's performance evaluation will be fully paid for and covered by the manufacturer. If WHO's performance evaluation is directly commissioned by the manufacturer (i.e., option A above), the manufacturer is responsible for directly paying all WHO's performance evaluation fees to the PEL and any other relevant person or entity. If WHO's performance evaluation is are directly commissioned and coordinated by WHO (i.e., option B above), the manufacturer is responsible for directly paying to WHO all WHO's performance evaluation fees including, but not limited to, WHO's coordination cost. Refer to the documents PQDx_458 "*WHO's performance evaluation procedure for in vitro diagnostics"* and PQDx_462 "*WHO's Performance evaluation fees"* for further information.

10. Attachments

Complete the table indicating that the required attachments are provided along with the completed EOI form including any comments if applicable.

11. Manufacturer Declaration

The manufacturer declaration appearing under Section 11 of the EOI Form must be completed, signed and dated on behalf of the manufacturer before the Expression of Interest form is considered for WHO's performance evaluation. The declaration must be completed, signed and dated by a duly authorized representative of the manufacturer designated under section 1.2 of the EOI Form.

12. Relevant Documents

The following documents provide information to guide the manufacturer through the process for WHO's performance evaluation of IVDs and are available on the WHO website: https://extranet.who.int/prequal/ivd-performance-evaluation:

- WHO's performance evaluation procedure for in vitro diagnostics. Geneva: World Health Organization; (PQDx_458)

- Eligibility criteria for WHO's performance evaluation of in vitro diagnostics. Geneva: World Health Organization; (PQDx_459)
- Expression of Interest form for WHO's performance evaluation of in vitro diagnostics. Geneva: World Health Organization; (PQDx_460)
- WHO's performance evaluation fees. Geneva: World Health Organization; (PQDx_462).

ISO standards

- ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes. Geneva: International Organization for Standardization (ISO). https://www.iso.org/iso-13485-medical-devices.html