ELIGIBILITY CRITERIA FOR WHO PREQUALIFICATION OF IN VITRO DIAGNOSTICS

Prequalification of In Vitro Diagnostics
1 Introduction
WHO Prequalification of In Vitro Diagnostics undertakes a comprehensive assessment of individual in vitro diagnostics (IVDs) 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.

2 Intended audience
This document has been prepared to provide manufacturers and other stakeholders with an overview of the eligibility criteria applied to products submitted for WHO prequalification assessment of IVDs. It is recommended that manufacturers wishing to apply for WHO prequalification of their product(s) read this document before applying for prequalification.

3 Eligibility for prequalification of IVDs
3.1 Original manufacturer
Applications for WHO prequalification of IVDs are accepted only from the legal manufacturer of the product.1

3.2 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 prequalification, and hence are not accepted for prequalification assessment.

3.3 Commercial availability
Applications for WHO prequalification of IVDs are only accepted for products that are commercially available at the time of submission for prequalification assessment. Any exemptions must be agreed upon by WHO prior to the submission of the application for prequalification.

1 The definition of a manufacturer is based on the definition used by the Global Harmonization Task Force (GHTF), and later adopted by the 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/
3.4 Eligibility principles
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 IVDs for a particular disease or disease state;
- Appropriateness of the product for use in resource-limited settings;
- Requests from WHO Member States for particular IVDs;
- Recommendation in WHO disease specific testing guidelines; and
- Availability of prequalified products that are of a similar assay format and/or assay principle.

3.5 Eligibility criteria
The eligibility principles are applied using the following eligibility criteria:

- Products that are manufactured by original product manufacturers;
- Products that are commercially available when submitted for prequalification assessment;
- Products of interest to UN organizations and other procurement agencies;
- Product categories for which there exists few other prequalified products.

The Prequalification Team currently accepts the following applications:

<table>
<thead>
<tr>
<th>Analyte/pathogen</th>
<th>Intended use</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Immunodeficiency virus</td>
<td>Diagnosis of infection</td>
<td>• Rapid diagnostic test (RDT)</td>
</tr>
<tr>
<td>HIV-1</td>
<td></td>
<td>• Enzyme immunoassays (EIA)</td>
</tr>
<tr>
<td>HIV-2</td>
<td>Self testing</td>
<td>• Nucleic acid testing</td>
</tr>
<tr>
<td></td>
<td>Monitoring of infection</td>
<td>• Flow cytometer for enumeration of lymphocyte subset including CD4+ T cells, or a technology that can be used at or near the patient (POC).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nucleic acid testing for measuring viral load</td>
</tr>
<tr>
<td>Hepatitis C virus (HCV)</td>
<td>Diagnosis of infection</td>
<td>• Rapid diagnostic test</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Enzyme immunoassays</td>
</tr>
<tr>
<td></td>
<td>Monitoring of infection</td>
<td>• Nucleic acid testing</td>
</tr>
<tr>
<td>Hepatitis B surface</td>
<td>Diagnosis and</td>
<td>• Rapid diagnostic test</td>
</tr>
</tbody>
</table>

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.

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.

3 Re-branded products are not accepted for prequalification assessment.

4 This document only applies to in vitro diagnostic medical devices. Male circumcision devices’ assessment eligibility criteria are defined in a separate document.
<table>
<thead>
<tr>
<th>Product</th>
<th>Diagnosis/Infection</th>
<th>Technologies/Formats to be Used at or Near to POC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antigen (HBsAg)</td>
<td>Monitoring of infection</td>
<td>Enzyme immunoassays</td>
</tr>
<tr>
<td>Malaria parasites</td>
<td>Diagnosis of infection</td>
<td>Rapid diagnostic test</td>
</tr>
<tr>
<td>Human papilloma virus (HPV)</td>
<td>Diagnosis of infection (for cervical cancer prevention)</td>
<td>Nucleic acid testing</td>
</tr>
<tr>
<td>G6PD enzyme</td>
<td>Enzyme deficiency detection</td>
<td>Technologies/Formats to be used at or near to POC</td>
</tr>
<tr>
<td>Toxigenic <em>Vibrio cholerae</em></td>
<td>Detection of outbreaks or surveillance for the disease</td>
<td>Rapid diagnostic test</td>
</tr>
<tr>
<td><em>Treponema pallidum</em> (Syphilis)</td>
<td>Screening and aid to diagnosis of infection</td>
<td>Rapid diagnostic test</td>
</tr>
</tbody>
</table>

### Table 1: Products currently eligible for prequalification assessment

The eligibility criteria are reviewed and amended in consultation with WHO Member States, other UN agencies, WHO programmes and technical experts.

The prequalification pre-submission form and supportive documentation will be reviewed against the above criteria to determine eligibility for prequalification assessment. If the product meets the WHO prequalification eligibility criteria the manufacturer will be informed on the next steps to be followed depending on the type of assessment (full or abridged) applicable to the product.

### 4 Relevant documents

The following documents provide information to guide the manufacturer through the requirements of the prequalification assessment:5

- Overview of the WHO Prequalification of in vitro diagnostics assessment: Document PQDx_007;
- Pre-Submission Form: Document PQDx_015;
- Instructions for the completion of the pre-submission form: Document PQDx_017.

### 5 Contact information

Any inquiries regarding WHO Prequalification of IVDs should be addressed to: diagnostics@who.int

---

5 These documents are available through the following website: [http://www.who.int/diagnostics_laboratory/evaluations/en/](http://www.who.int/diagnostics_laboratory/evaluations/en/)