Prequalification of in vitro diagnostics: consultation on eligibility - Introduction

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**IVDs and access**

Access to IVDs heavily impacts the majority of medical decisions, including blood safety, surveillance, diagnosis and treatment initiation and monitoring.

To achieve such impact IVDs must be safe and of good quality.

Access to quality assured IVDs is a key enabler for an efficient health service, including at PoC and contributes to:

- advancing UHC
- promoting healthier populations
- addressing public health emergencies
PQDx: a tool towards improved access

- The aim of PQDx is to promote and facilitate access to safe, appropriate and affordable IVDs of good quality.
- Focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings.
- The findings of PQDx are used to provide independent technical information on safety, quality and performance of IVDs, principally to other UN agencies but also to WHO Member States and other interested organizations.
- The PQDx status, in conjunction with other procurement criteria, is used by UN agencies, WHO Member States and other interested organizations to guide their procurement of IVDs.
PQDx: a tool towards improved access

- Quality assured IVDs
- Product selection options for procurers and MSs
- Healthy competition
- Fair pricing
- Innovative products

Improved access

- UHC
- SDGs
- WHA resolutions
- WHO impact goals
PQDx components

PQDx undertakes a comprehensive assessment of individual IVDs through a standardized procedure aimed at determining if the product meets WHO prequalification requirements.

The prequalification assessment process includes three components:

- Dossier review
- Site inspection
- Performance evaluation
Prequalification: decision

- Final prequalification outcome depends on:
  - Results of dossier assessment
  - Results of inspection(s)
  - Meeting the acceptance criteria for the laboratory evaluation

- WHO PQDx Public Report is posted on WHO website and product is added to the list of WHO prequalified products

- Product is then eligible for WHO and UN procurement
PQDx eligibility: current status
PQT has shaped the prequalification programme scope according to requests received from:

• WHO disease programs; and

• main international procurers.

<table>
<thead>
<tr>
<th>timeline</th>
<th>IVD type</th>
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<tbody>
<tr>
<td>Since 2008</td>
<td>HIV and malaria</td>
</tr>
<tr>
<td>Since 2014</td>
<td>Hepatitis B and C</td>
</tr>
<tr>
<td>Since 2016</td>
<td>HPV</td>
</tr>
<tr>
<td>Since 2017</td>
<td>G6PD</td>
</tr>
<tr>
<td>Since 2018</td>
<td>Cholera</td>
</tr>
<tr>
<td>As of 20 March 2019</td>
<td>Syphilis</td>
</tr>
</tbody>
</table>
1. **Original manufacturer**
   - No re-branded products are accepted

2. **Commercial availability**
   - Products commercially available at the time of submission

3. **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.
4. 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.

5. Current scope:

HIV, malaria, hepatitis B and C, HPV, G6PD, Cholera

Syphilis as of 20 March 2019
PQDx eligibility: future
Current PQDx eligibility

PQT has shaped the prequalification programme scope according to requests received from

• **WHO disease programs** and

• the **main international procurers**

PQT received several requests to expand the PQDx scope, including for infectious diseases, NTDs and NCDs, however:

• Need for a **strategic approach** defining future priorities and determining how PQ can have the greatest impact on access

• Need to **communicate** future PQDx direction to stakeholders, including Member States, donors and manufacturers
At SAGE-IVD 2018 it was agreed to develop a new eligibility determination process:

- less dependent on individual requests; and
- more inclusive of the various public health elements, including other health interventions supported through WHO
WHO consultation on PQDx eligibility: working towards improved access

• to gather key stakeholders, including key international procurers and WHO disease programs, to determine the types of IVDs for which PQ is most needed and for which it will have the greatest public health benefit.

• to map the most needed quality assured IVDs and to embrace the following concepts:
  
  • the burden of disease;
  
  • health interventions associated with particular IVDs;
  
  • existing WHO guidelines;
  
  • EDL listing (if available prior to the consultation);
  
  • available/expected donor funding.
WHO consultation on PQDx eligibility: working towards improved access

Consultation took place Nov 2018 – Jan 2019

Stakeholders were requested to respond to the survey

Form: Request for the addition of an IVD type to Prequalification of in vitro diagnostics eligibility criteria

- To document requests for addition to the PQDx eligibility
- To capture key information in support of the eligibility decision
Way forward

Survey outcomes will be presented
Stakeholders are welcome to comment

SAGE-IVD will discuss and prepare a proposal to WHO

WHO will decide on future PQDx eligibility
Final outcome:
1. List of IVDs to be added to PQDx eligibility;
   and
2. The respective timelines
Expected impact of PQDx expansion

- Expanded list of quality assured IVDs for priority diseases
- Improved access
- UHC