

## *Prequalification of Diagnostics*

Update

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*This issue of the Prequalification of Diagnostics Update provides information about the applications received thus far and describes the priority setting for applications.*

### **Applications received**

WHO continues to accept applications from manufacturers of currently available diagnostics for priority diseases. WHO has received applications from 25 manufacturers for the prequalification of diagnostics programme. A total of 79 applications were received comprising 26 HIV rapid tests, 8 other types of HIV assays, 14 hepatitis C assays, 7 hepatitis B assays and 24 malaria assays. For the current status of the review of applications see [www.diagnostics\\_laboratory](http://www.diagnostics_laboratory).

#### **Important note**

The prequalification of diagnostics programme replaces the former WHO test kit evaluation procedure. Any manufacturer who has previously requested a test kit evaluation or who is interested in prequalification of their diagnostic products is invited to apply via the application to the prequalification of diagnostics programme available at [www.who.int/diagnostics\\_laboratory](http://www.who.int/diagnostics_laboratory).

### **Priority setting for the prequalification of diagnostics 2009**

In order to meet the needs of WHO Member States and UN agencies, conditions for prioritization have been established and are reviewed and updated every 6 months. Although all applications received from manufacturers will be reviewed and responded to, those products meeting one or more of the following criteria will be given priority for prequalification:

1. Diagnostics already listed on the WHO procurement scheme and procured by UN organizations in significant levels.
2. Products which assist in the diagnosis of infection with HIV-1/HIV-2 and infection with malaria parasites.
3. Diagnostics in a rapid test format.
4. Diagnostics that are manufactured by original product manufacturers.
5. Product categories for which there exists few other prequalified products.

WHO reserves the right to prioritize diagnostics according to other criteria dependant on changing global health needs, the particular needs of WHO Member States, and the emergence of new and relevant diagnostic technologies.

#### **Reminder**

*All correspondence and inquiries regarding prequalification should be addressed to [diagnostics@who.int](mailto:diagnostics@who.int).*

*When sending correspondence referring to specific applications, always use the prequalification tracking number. This speeds up the response to any queries.*

## Frequently asked questions

### ***How can a manufacturer find out about the status of the application?***

WHO has been prioritizing and reviewing applications (see [www.who.int/diagnostics\\_laboratory](http://www.who.int/diagnostics_laboratory) for the list of accepted applications). Applications which are incomplete, applications with information which differ from the instructions for use and clarity of instructions for use are issues that will extend the time needed for the review process.

### ***If a product has already undergone a WHO test kit evaluation, is it necessary to redo the full prequalification of diagnostics assessment, including the laboratory evaluation?***

A manufacturer who has submitted a product for evaluation under the previous WHO laboratory evaluation procedure will need to submit an application to the prequalification programme. If accepted, the manufacturer will be requested to submit a dossier and a manufacturing site inspection will be required.

### ***If a manufacturer has a product which meets the priority criteria, can the dossier be sent for evaluation?***

Dossier submission is upon invitation only. If an application to the prequalification programme has been accepted, the manufacturer will be requested to sign a letter of agreement and to pay a fee before sending the dossier.

### ***If a product is not priority does that mean that it will not be accepted for a prequalification assessment?***

The priority setting has been put into place as a temporary measure during the transitional period during which WHO moves from the previous test kit evaluation procedure to the prequalification of diagnostics programme and allows WHO to accelerate the application review process. Priority criteria will be reviewed two times a year and will be modified if necessary according to the needs of Member States and UN agencies.

### ***Is it necessary to show certification of approval from a conformity assessment body in order to apply to the prequalification of diagnostics programme?***

WHO seeks information in the application form concerning product approvals from recognized institutions. Proof of approval is required upon submission of the dossier. However, approval from a notified body is not a prerequisite for prequalification.

### ***Is prequalification equivalent to approval from a national competent authority?***

No. Prequalification enables a product to become eligible for tender for procurement by UN organizations. It does not replace country specific registration or approval, nor is it a certification from a conformity assessment body, but it represents an assessment of the quality of diagnostic products and indicates their suitability for use in resource-limited

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