

Prequalification of Diagnostics

Update

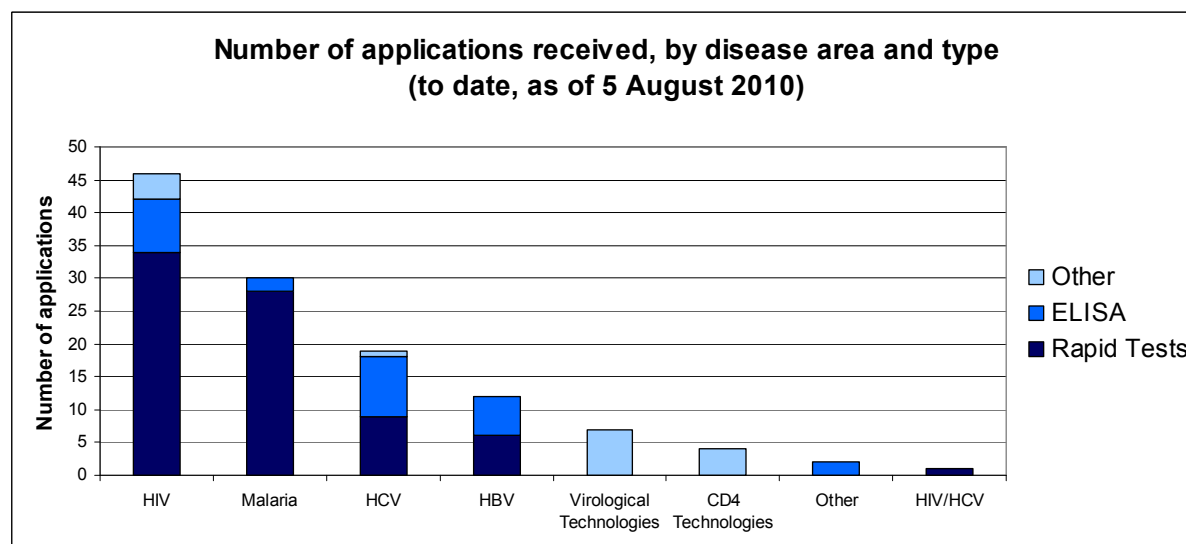
Issue 4
Q3 2010

This issue of the Prequalification of Diagnostics Update provides information on applications, dossiers and inspections, and reviews issues pertaining to potential fast track consideration.

Applications received

WHO continues to accept applications from manufacturers of currently available diagnostics for priority diseases. As of 5 August 2010, WHO has received a total of 121 applications to the Prequalification of Diagnostics Programme, including 34 HIV rapid tests, 12 other types of HIV-related assays, 19 hepatitis C assays, 12 hepatitis B assays and 30 malaria assays.

Detail on the status of applications is available at www.who.int/diagnostics_laboratory.



Dossiers submitted

As of 5 August 2010, applications for 27 diagnostics have been prioritized for invitation to submit a prequalification dossier. In response, 14 dossiers have already been received, and 5 more are expected by the end of Q3 2010.

The Diagnostics and Laboratory Technology team is now performing initial screening and coordinating subsequent in-depth review of these dossiers.

Inspection planning

In parallel to the above activities, inspections for several manufacturing sites are being scheduled from Q3 2010.

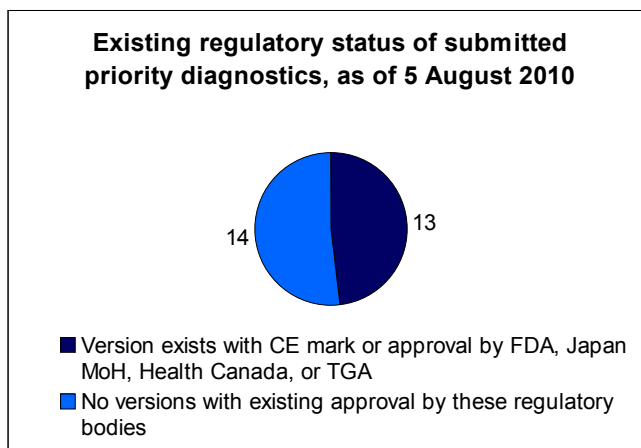
Reminder

All correspondence and enquiries regarding prequalification should be addressed to diagnostics@who.int. In correspondence referring to specific applications, always include the prequalification tracking number to facilitate a response to any query.

Priority submissions and fast track procedures

Of 27 prioritized diagnostics, approximately half have versions approved by stringent regulatory authorities (e.g., Food and Drug Administration approval in the United States, CE mark for market authorization in Europe, Ministry of Health approval in Japan); see figure at right.

WHO is establishing fast track procedures where possible to increase efficiency and to avoid duplicating efforts.



While developing the fast track procedures, WHO has identified several issues that may impact fast tracking, including:

- Existence of multiple regulatory versions of a product, lack of clarity on differences between regulatory versions, and/or lack of transparency on the version submitted for prequalification
- Differences in regulatory oversight and/or requirements between authorities (e.g., Food and Drug Administration approval vs. CE mark)
- Differences in the stringency of regulatory approval across diseases (e.g., requirements for approval of a diagnostic in malaria vs. HIV)

WHO will continue to work to identify where prequalification assessment and inspection processes may be fast tracked, and in the meantime WHO will work closely with applicants where clarification is required.

Prequalification of Diagnostics information session

WHO will offer an information session on 17 November 2010, in Düsseldorf, Germany. In the session, WHO will provide an update on prequalification and fast track procedures, and address a range of frequently asked questions related to dossier review and manufacturing site inspections conducted to date.

- What: WHO Prequalification of Diagnostics Programme information session
- Who: Manufacturers of diagnostics for HIV, HBV, HCV, and malaria
- Where: Maritim Hotel Düsseldorf, Maritim-Platz 1 (connected to Düsseldorf airport)
- When: 17 November 2010, 9-11 am

Please note that space is limited: if you are interested in attending, please email diagnostics@who.int to register. In your email, please specify the names of those planning to attend (maximum 3 people per company).

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www.who.int/diagnostics_laboratory