

Prequalification of Diagnostics

Update

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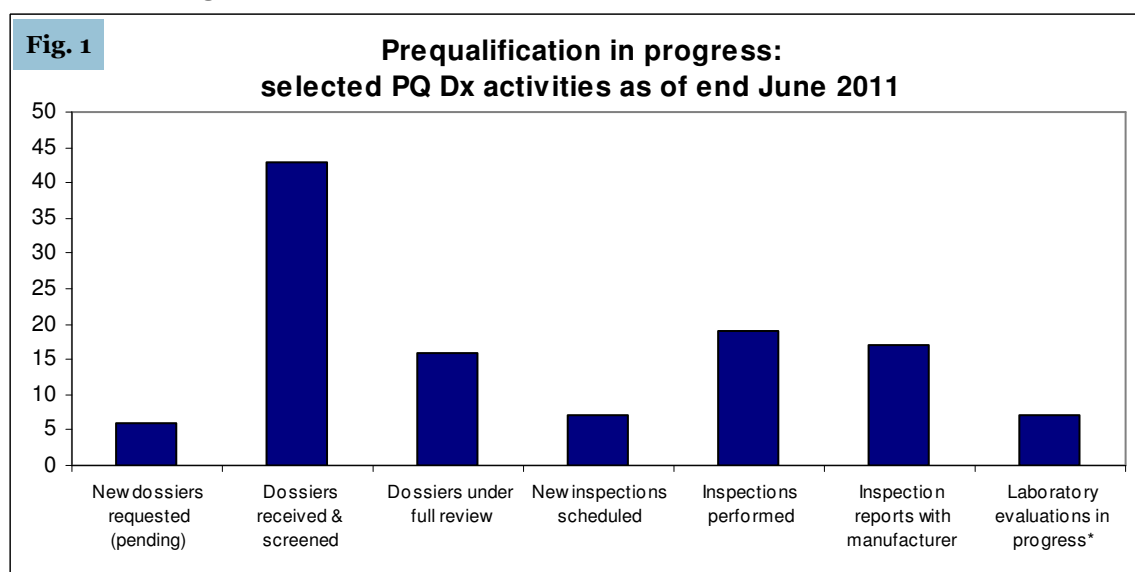
This issue of the Prequalification of Diagnostics Update provides information on applications, dossiers and inspections, including feedback based on lessons learned.

Progress on Prequalification of Diagnostics in 2011

In the first half of 2011, the Diagnostics and Laboratory Technology team has made steady progress in the prequalification of priority diagnostics.

To date, 66 applications have been reviewed; of these, 55 have been accepted, and 11 have been closed. Of 43 dossiers received, almost 90% have been screened for completeness. Following resolution by the manufacturer of issues identified in initial dossier screening, 16 dossiers have proceeded to the full review stage, with assessments completed for over half of these. Six new dossiers are expected to arrive in the coming months.

In parallel, manufacturing site inspections have been conducted for 19 products, with inspections for an additional 7 products scheduled. Follow-up for completed inspections is ongoing, with 17 full inspection reports already sent to manufacturers. Laboratory evaluations are ongoing for 8 HIV rapid diagnostic tests (RDTs). Progress in selected activities are shown in Figure 1.



The remainder of this update provides more information on the laboratory evaluation component of WHO Prequalification of Diagnostics for products other than malaria RDTs.*

* For malaria RDTs, the Diagnostics and Laboratory Technology team refers to product testing data from WHO FIND Malaria RDT Product Testing.

Reminder

All correspondence and enquiries regarding prequalification applications and dossiers 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.

Why does WHO perform laboratory evaluations?

WHO coordinates laboratory evaluations, carried out by WHO Collaborating Centres, to verify the performance claims and to obtain practical information on operational characteristics of particular diagnostics. Aspects assessed depend on the type of technology, but may include sensitivity, specificity, inter-reader variability, rate of misclassification, repeatability and/or reproducibility in comparison with established performance criteria or reference methods. WHO also focuses on the perspective of end users in low-income countries, assessing the suitability of the assay for use in testing settings with less skilled operators and limited infrastructure and/or support including maintenance and training.

WHO sends the evaluation protocol and details of evaluation logistics to the manufacturer in advance. This communication contains all required information, but additional tips for consideration while preparing are outlined below.

Tips for success in preparing for the laboratory evaluation

The points below are based on lessons learnt through initial programme activities. In this issue, our focus is on laboratory evaluations; please refer to earlier issues for information on product dossier review and manufacturing site inspections. Please note that these highlights are not intended as an exhaustive guide to WHO Prequalification of Diagnostics.

Preparing for the laboratory evaluation

- Consider demonstrating the test procedure at the WHO Collaborating Centre
 - Before the official evaluation commences, the manufacturer is invited to visit the WHO Collaborating Centre for one day to demonstrate the test procedure
 - The demonstration will be run exactly as described in the instructions for use; as a rule, no changes to the test procedure as stated in the instructions for use may be made
 - Anticipate the need to supply tests from normal production batches for the laboratory evaluation, plus required test kit controls and/or calibrators if not included in the test kit
 - Send test kits as outlined in instructions received from the WHO Collaborating Centre
 - Do not send diagnostic tests to the WHO Collaborating Centre unless expressly invited to do so. Any tests sent to a WHO Collaborating Centre without invitation will not be accepted
 - Send test kits at the beginning of the week to allow sufficient time for airport clearance during the working week – i.e., avoid test kits being held at the airport over the weekend. If possible, provide shipping information and an airway bill number for the WHO Collaborating Centre
 - Inform WHO if specific equipment is required for performance of the evaluation. If critical for the evaluation, the equipment must be provided by the manufacturer free of charge (including importation, installation, maintenance during testing and removal at the end of the study, if applicable)
 - Ensure that the product and regulatory version(s) provided match those considered during product dossier and manufacturing site inspection
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