



Prequalification of Diagnostics

Update

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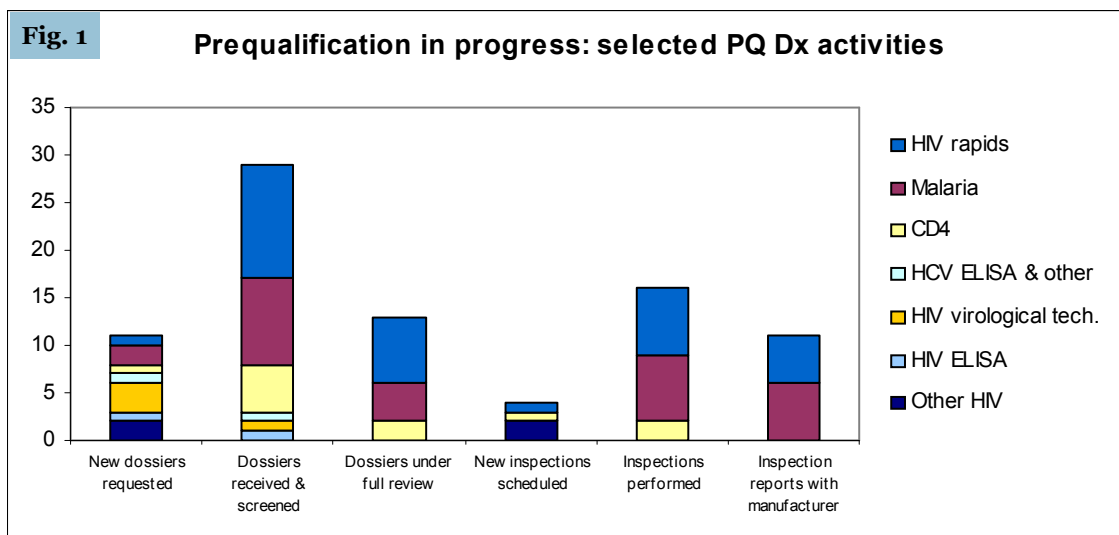
This issue of the Prequalification of Diagnostics Update provides information on applications, dossiers and inspections, including feedback based on lessons learned.

A robust prequalification pipeline and early progress in 2011

Since announcing its first prequalified product in December 2010, the Diagnostics and Laboratory Technology team has focused on the pipeline for 2011.

To date, over 50 applications have been accepted, and 41 signed letters of agreement have been received. Of 29 dossiers received to date, all have been screened for completeness, and the team is now working with manufacturers to address any amendments required before the dossiers can proceed to full review. Thirteen dossiers, for HIV CD4, HIV and malaria rapid diagnostic tests, are under full review. A further 11 new dossiers have been requested and are expected in the coming months.

In parallel, manufacturing site inspections are ongoing, with inspections for 16 products performed and 4 additional confirmed as of the end of March 2011. Inspections this year include manufacturing sites for CD4 and HIV virological technologies. Laboratory evaluations are also being scheduled. Progress in selected product-specific activities are shown in Figure 1.



The rest of this update provides more information on the manufacturing site inspection, including reasons for WHO inspections and tips for preparing for the inspection. Laboratory evaluations will be explored in a future issue.

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 inspect the manufacturing site?

WHO conducts manufacturing site inspections to:

- Verify quality management system (QMS) claims, implementation, and effectiveness
- Provide immediate feedback to manufacturers, highlighting areas to improve quality of manufacturing
- Strengthen national regulatory capacity

That is, the inspection allows WHO to assess the adequacy of the manufacturer's QMS and correct implementation of documented procedures. As importantly, the inspection verifies that the QMS is effective in ensuring that a good quality diagnostic is manufactured consistently. WHO procedures are based on internationally recognized standards including ISO 13485:2003 and Global Harmonization Task Force (GHTF) guidelines. The WHO inspection is product-specific, and the production line is examined in detail. WHO inspections emphasize customer requirements for in-use, transport and storage stability – key areas of concern for end users. WHO inspection findings on these and other areas often have been significant even for experienced manufacturers.

Tips for success in preparing for the manufacturing site inspection

The points below are based on lessons learnt through initial programme activities. In this issue, our focus is on the manufacturing site inspection; future issues will address laboratory evaluations. Please note that these highlights are not intended as an exhaustive guide to WHO Prequalification of Diagnostics. For detailed guidance, please refer to the information on our website at:

http://www.who.int/diagnostics_laboratory/evaluations/PQDxSiteInspection/en/index.html

Preparing for the manufacturing site inspection

- Ensure the site is in active production for the relevant product(s) during the inspection
- Define and agree on inspection objectives and scope with the WHO inspection team
- Inform the WHO inspection team of any issues that may affect an efficient and effective inspection process
- Ensure that key personnel are present at the time of the inspection
 - Identify a person responsible for coordinating and facilitating the inspection
 - Appoint responsible members of staff to accompany the WHO inspection team and to inform inspectors of health, safety and other requirements
 - Inform relevant employees about the inspection objectives and scope
 - Consider the need for interpreters; the inspection is conducted in English
- Provide on-site resources, such as a meeting room, for the inspection team
- Provide timely access to the manufacturing facilities, documents and records and other evidence requested by the inspectors; this may include:
 - Raw data supporting dossier claims on performance and stability
 - Validation and verification of key suppliers of materials used in manufacturing

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