

Prequalification of Diagnostics

Update

Issue 8
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This issue of the Prequalification of Diagnostics Update provides information on the fast track procedure.

Fast track procedure now available

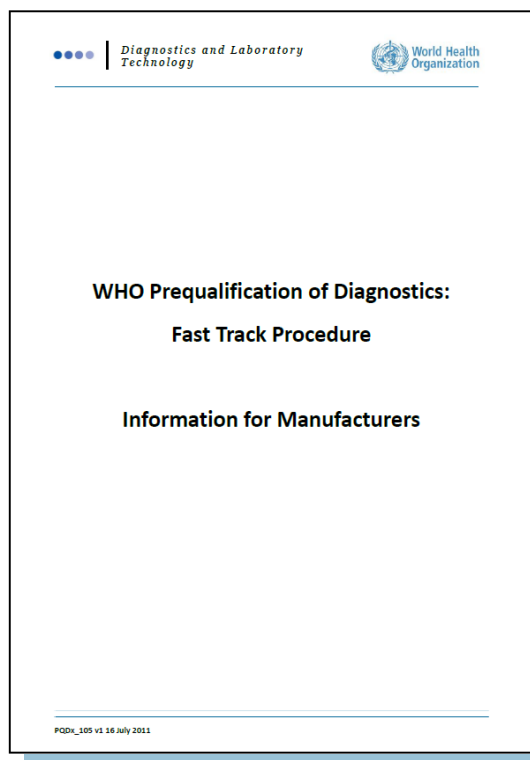
What is fast tracking?

Some diagnostics submitted for WHO prequalification have been previously assessed by one or more National Regulatory Authorities. Prior regulatory approval can play an important role in accelerating the WHO prequalification assessment. Where the same evidence is required for both stringent regulatory review and for WHO prequalification, the potential exists for WHO to conduct an abbreviated assessment – the fast track procedure. The aim of the fast track procedure is to avoid duplication of effort and reduce the time to prequalify products.

The decision by WHO to conduct an abbreviated assessment is based on several factors and is made on a case-by-case basis. WHO will always undertake some level of assessment of the product and its manufacture to provide assurance relating to unique aspects of quality, safety and performance – e.g., to verify the identity of the product and to ensure its suitability for use in resource-limited settings.

Depending on the evidence provided for prior stringent regulatory approval, WHO may expedite the prequalification process by:

- Reviewing in-depth only those aspects of the product dossier that are specific to the WHO Prequalification for Diagnostics programme, and/or
- Conducting a shortened inspection focused on aspects related to the perspective of WHO end users (e.g. transport/storage stability, customer service networks, etc.).



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.

Where can I find more information?

More information on the fast track procedure is now available on our website:

http://www.who.int/diagnostics_laboratory/110816_pqdx_105_fast_track_procedure_information_for_manufacturers.pdf

This document is intended for manufacturers who apply to the WHO Prequalification of Diagnostics Programme, but may also be useful for end users, procurement agencies and national regulatory authorities in low- and middle-income countries.

Ongoing prequalification activities



To date, 150 prequalification applications have been received and are in various stages of the prequalification process. Twenty-

one applications have been closed for various reasons. Fifty-seven dossiers have been received; screening and full assessment are underway. Full assessment has been completed for 19 products. Manufacturing site inspections for 31 products have been conducted. Another 6 have been scheduled for Q4 2011 and Q1 2012, and further scheduling is ongoing. Laboratory evaluations for 13 HIV products (mainly rapid tests) are in progress, with 6 expected for completion by the end of 2011. An additional 9 HIV products are scheduled for evaluation in Q1 2012.

Detailed information on the status of each product currently under review can be found at: http://www.who.int/diagnostics_laboratory/pq_status/en/index.html.

Focus on HIV Viral Load Technologies

On 17 October 2011, the WHO Prequalification of Diagnostics programme added the products below to WHO list of prequalified diagnostic products.

- Abbott RealTime HIV-1 (Manual)
- Abbott RealTime HIV-1 (m2000sp)
- Abbott RealTime HIV-1 (m24sp)

For details including product codes and manufacturing site, please refer to: http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/index.html

Prequalification activities for several other HIV viral load technologies are in progress, with 5 dossiers under assessment. Fast tracking of these products has been made possible by prior stringent regulatory approval (assessed on a case-by-case basis) leading to a reduction in the time to prequalification. Prequalification decisions for these products are anticipated in Q4 2011.

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