

## *Prequalification of Diagnostics*

Update

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*This issue of the Prequalification of Diagnostics Update marks the launch of the prequalification of diagnostics programme and aims to address the most frequently asked questions about the programme.*

### **Questions about the prequalification of diagnostics process**

#### ***Who can apply?***

WHO will accept applications from manufacturers for HIV, malaria and hepatitis diagnostics which meet the needs of WHO Member States. Rapid tests will be given priority.

#### ***When will manufacturers be able to apply?***

The official launch of the prequalification programme will take place on 16 June 2008. The prequalification of diagnostics application form and instructions for submission will be available on the WHO Diagnostics and Laboratory Technology website as of that date. Manufacturers who have previously requested a WHO evaluation will be invited to complete an application.

#### ***How can I get more information on the programme?***

Regular updates will be available on the Diagnostic and Laboratory web pages after the launch.

#### ***What happens after an application is submitted to WHO?***

The application will be reviewed and upon acceptance, the manufacturer will be requested to sign a letter of agreement, pay a fee and submit a product dossier.

#### ***How much is the fee?***

The amount required to proceed with the prequalification assessment is US\$ 12,000.

#### ***Will manufacturers who already have products on UN procurement lists be required to submit an application?***

Yes. The requirements for UN procurement listing have become more rigorous to include a dossier review and an inspection of the manufacturing site, in addition to a laboratory evaluation (see Update 1). Thus, all manufacturers who aim to have products on UN procurement lists, including those with products already on the lists, should submit an application for a full prequalification assessment.

#### ***How long will the application process take?***

The length of time to review the applications will depend on the number of applications received, the priority of the product and the completeness of the applications.

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### ***What is the purpose of the dossier review?***

The dossier is reviewed with the purpose of gaining an understanding of the manufacturer's production process; the operation and performance of the product; and determining if the product is ready for a laboratory evaluation and site inspection.

### ***How long will the dossier review take?***

Complete and good quality dossiers can be reviewed in approximately 2 weeks. However, turn around time for individual dossiers depends on the number of dossiers under review at that time and the completeness and quality of the submitted dossier. If a dossier is not complete, the manufacturer will be requested to submit additional information within a specified time period. Failure to provide the requested information within three months will delay or halt the review process.

### ***What happens after the dossier review?***

Once a dossier has been reviewed and found to be satisfactory, the prequalification will proceed to the laboratory evaluation and the manufacturing site inspection. Scheduling issues will determine which comes first.

### ***How is the laboratory evaluation carried out***

The laboratory evaluations are carried out by specific WHO Collaborating Centres in coordination with WHO and assess the technical performance and operational characteristics of a product. The technical performance evaluation includes sensitivity, specificity and predictive values, as well as reader variability for rapid tests. The operational characteristics are reviewed for the suitability of the product for testing services in resource-limited settings.

### ***How can the manufacturing site inspection be prepared for?***

There are several resources available online which provide guidance on quality management systems: the International Organization for Standardization at [www.iso.org](http://www.iso.org); the web site of the Global Harmonization Task Force at [www.ghtf.org](http://www.ghtf.org); and the WHO publication, Medical Device Regulations at [www.who.int/medical\\_devices/publications](http://www.who.int/medical_devices/publications).

### ***Does prequalification guarantee that a product will be included in UN or other procurement schemes?***

If a product is found to have met the prequalification requirements then it can become eligible for inclusion in UN procurement tenders. Nevertheless, additional procurement criteria will be applied before final selection.

### ***If a company already has certification from a stringent regulatory authority, is it still necessary to undergo the prequalification assessment?***

Yes. Currently, all products to be procured by UN agencies need to undergo prequalification assessment as the conditions in countries with stringent regulations are different from resource-limited settings. However, if a company has such a certification this may speed up the process.

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