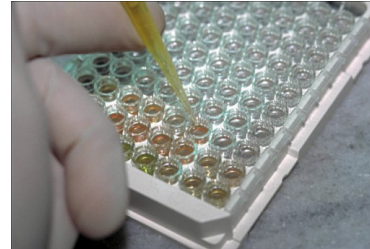


Prequalification of Diagnostics

Update

Issue 1
Q1 2008

The new Prequalification of Diagnostics Update aims to inform readers about the programme, its progress and plans. This update is a first of a series of quarterly issues designed to keep donors, manufacturers, procurement officials and other stakeholders informed. The information update will also be available on our web pages.



About Prequalification of Diagnostics

Prequalification of diagnostics is a programme that aims to increase access to affordable diagnostic technologies of assured quality that are appropriate for use in resource limited settings. This is achieved by providing information on the technical findings of the assessment to WHO Member States, United Nations agencies and other key stakeholders.

WHO has carried out laboratory evaluations of the performance and operational characteristic of diagnostics since 1988. In 2008 the programme is being strengthened in order to increase stringency and efficiency of prequalification of priority HIV/AIDS and malaria diagnostics. The programme comprises:

- an application and a dossier review,
- a laboratory evaluation of the performance and operational characteristics of the product and
- an inspection of the manufacturing site for compliance with globally recognized quality standards.

Prequalification, in addition to other criteria, enables a product to be eligible for procurement by the UN and NGOs in official relations with WHO.

The Need for Prequalification

Access to treatment and care for HIV/AIDS, tuberculosis and malaria is increasing in many resource limited countries, however in order to achieve the Millennium Development Goals access to quality diagnostics is still needed. Regulatory capacity is limited in many countries, allowing poor quality diagnostics to enter markets.

Access to affordable, quality diagnostics which are safe and appropriate for their intended use leads to more efficient spending of public monies and contributes to:

- an increase in the number of patients who know their disease status, ensuring blood safety and enhancing prevention efforts
- improved impact of treatment by reducing wastage resulting from unnecessary treatment
- improved patient outcomes

Diagnostics play a critical role in ensuring blood safety, surveillance, diagnosis and treatment initiation and monitoring.

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The Prequalification of Diagnostics Process

The application and dossier review

The first stage of the prequalification of diagnostics process includes an application and a dossier review. Applications from manufacturers with priority diagnostics which serve the needs of WHO Member States take precedence. Once an application is accepted, the manufacturer will be invited to submit a dossier, sign an agreement and pay an assessment fee.

The dossier is reviewed with the purpose of gaining an understanding of the product and how it performs; gaining an understanding of the manufacturing process; determining if the product is suitable for WHO Member States; determining if the product is ready for a laboratory evaluation and site inspection.

If the dossier is not complete, the manufacturer will be requested to submit additional information within a specified time period. Once a dossier is accepted, the prequalification will proceed to the laboratory evaluation and the manufacturing site inspection.

The laboratory evaluation

The laboratory evaluation is carried out by a WHO Collaborating Centre and assesses the technical performance and operational characteristics of a product. The technical performance includes the sensitivity, specificity and predictive values, as well as the accuracy and reproducibility in comparison with established criteria. The operational characteristics are reviewed for their suitability for use in laboratories in resource-limited settings.

The manufacturing site inspection

The manufacturing site inspection is carried out to assess the adequacy and effectiveness of the manufacturer's quality management system and the correct implementation of documented procedures. The inspection is based on internationally recognized standards and is carried out by a WHO inspector, an external inspector and observers from National Regulatory Authorities.

Prequalification outcome

If a product is found to have met the prequalification requirements then it can become eligible for inclusion in UN procurement tenders. Summary reports of the laboratory evaluation and the site inspection will be made publicly available on the WHO website.

Schematic Representation of the Prequalification of Diagnostics

