

Prequalification of diagnostics programme: update

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World Health
Organization

Role of WHO prequalification

WHO prequalification:

- Diagnostics
- Medicines
- Vaccines

Facilitate access to safe, appropriate priority diagnostics, medicines & vaccines

Support two of WHO's six core functions:

- setting norms & standard/promoting their implementation
- providing technical support, catalysing change & building institutional capacity)

Contribute to achieving four of WHO's impact goals:

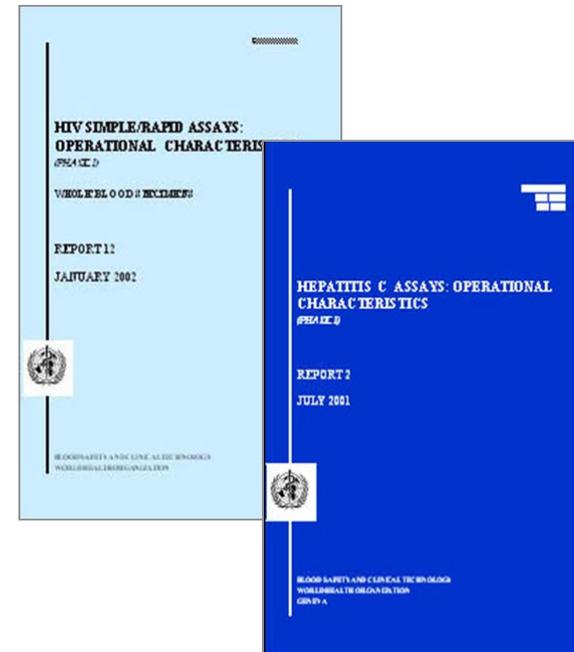
- reduce under-five mortality
- reduce maternal mortality
- reduce the number of people dying from AIDS, tuberculosis and malaria
- eradicate polio)



WHO work in Dx

WHO has been assessing diagnostics performance and operational characteristics since 1988

- HIV assays since 1988
- Hepatitis B assays since 2000
- Hepatitis C assays since 2000
- Syphilis assays since 2001
- Chagas assays since 2002
- Malaria assays since 2002
- CD4 technologies ad-hoc in 1996 & 2003



2008: PQDx launch

Shift from test kit evaluations to prequalification of diagnostics:

- More stringent approach
- Alignment with global standards for assuring quality of diagnostics

Through a rigorous process identify diagnostics that meet the quality standards



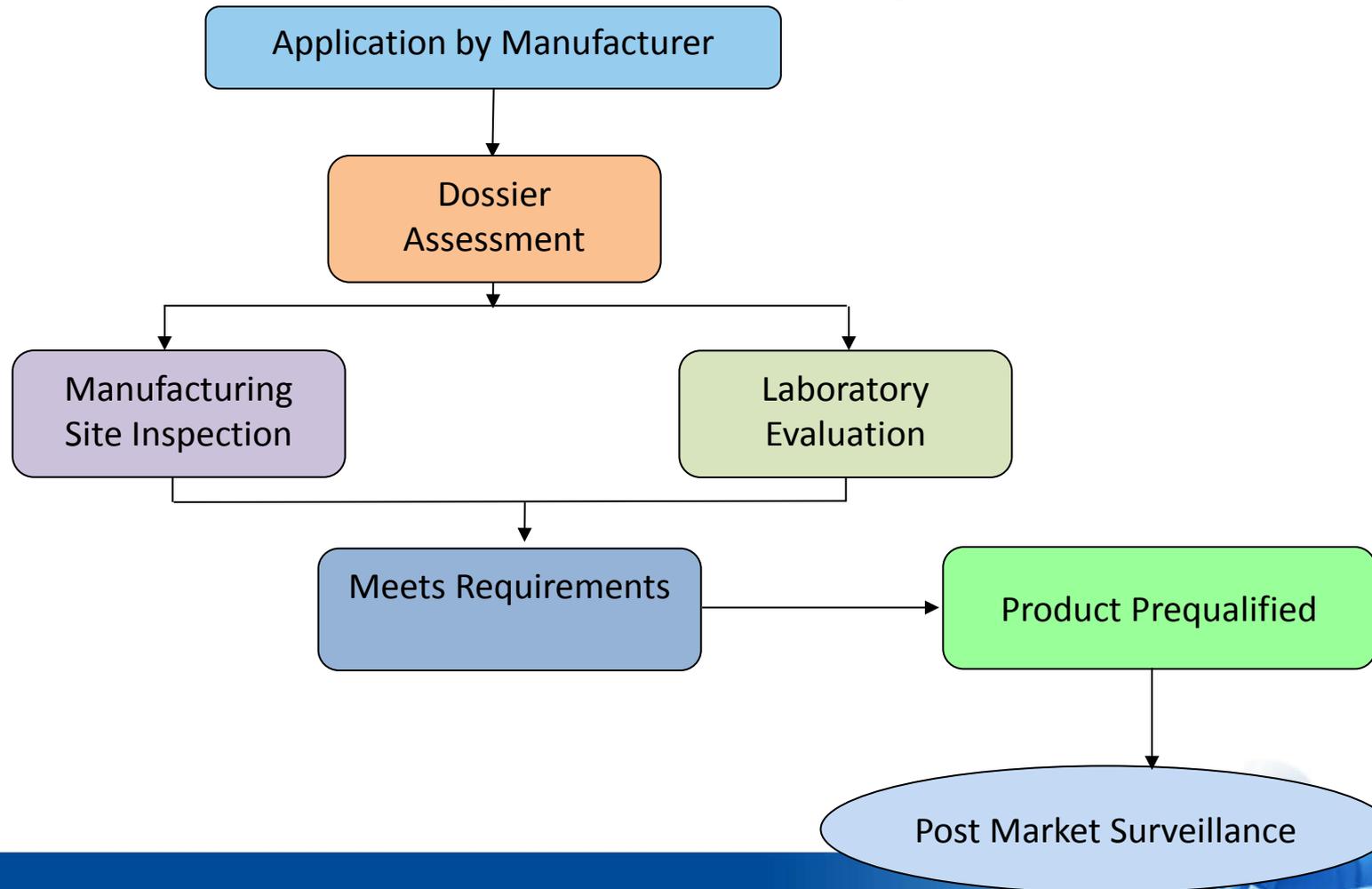
Prequalification of diagnostics programme

The prequalification of diagnostics programme has four components:

- An application to the programme and a dossier review
- An inspection of the manufacturing site to assess compliance with international QM standards
- A laboratory evaluation to assess performance and operational characteristics of the product
- Building of regulatory capacities, including post-market surveillance of diagnostics



Prequalification of diagnostics programme



Prequalification of diagnostics: impact

The programme provides Member States, UN agencies and other partners with technical information and advice on the quality of currently available HIV/AIDS, malaria and hepatitis B and C test kits and technologies.

Prequalification of diagnostics is a prerequisite for UN procurement ensuring that public monies are spent in a cost effective manner, on quality diagnostics.

A range of good quality diagnostics appropriate for all levels of the health system in resource limited settings

Increased access to quality diagnostics at reduced prices

Improved access to impartial technical information on diagnostics

Improved capacity at country level to monitor the quality of diagnostics on their market



Prequalification of diagnostics: streamlining

Review of experience, analysis of gaps and challenges

Way forward: streamlined PQDx

- Increase efficiency (improve timelines)
- Improve transparency (requirements, process)
- Show how PQDx can best work with key partners (manufacturers, procurement and other agencies, NRAs)
- Strengthen communications



Prequalification of diagnostics: streamlining

Process

Pre-dossier phase (application form)

- Prioritization and pre-acceptance of dossier for full assessment

Product dossier

- Guidance, partners' work

Inspections

Lab evaluations: protocols, partners' work

Fast track for Dx with SRA approval



Prequalification of diagnostics: streamlining expected outcomes:

Increased efficiency and transparency

Clean pipeline

- Better focus on active applications

Robust capacity building programme in place:

- advisory visits to tackle specific gaps and
- training programme to address most common PQ issues

Additional guidance to be developed to assist Mx / training plan for priority topics



Stakeholders engagement

Ongoing discussions with partners to identify areas of overlap and opportunities for collaboration

What information can fit into PQDx dossier, inspections lab evaluation keeping the PQ quality standards

How can PQDx fit into other bodies QA mechanisms

Working towards Common WHO/USAID list of Dx

Establish and communicate 2014 agenda

04 April 2014: stakeholders consultation in GVA

