

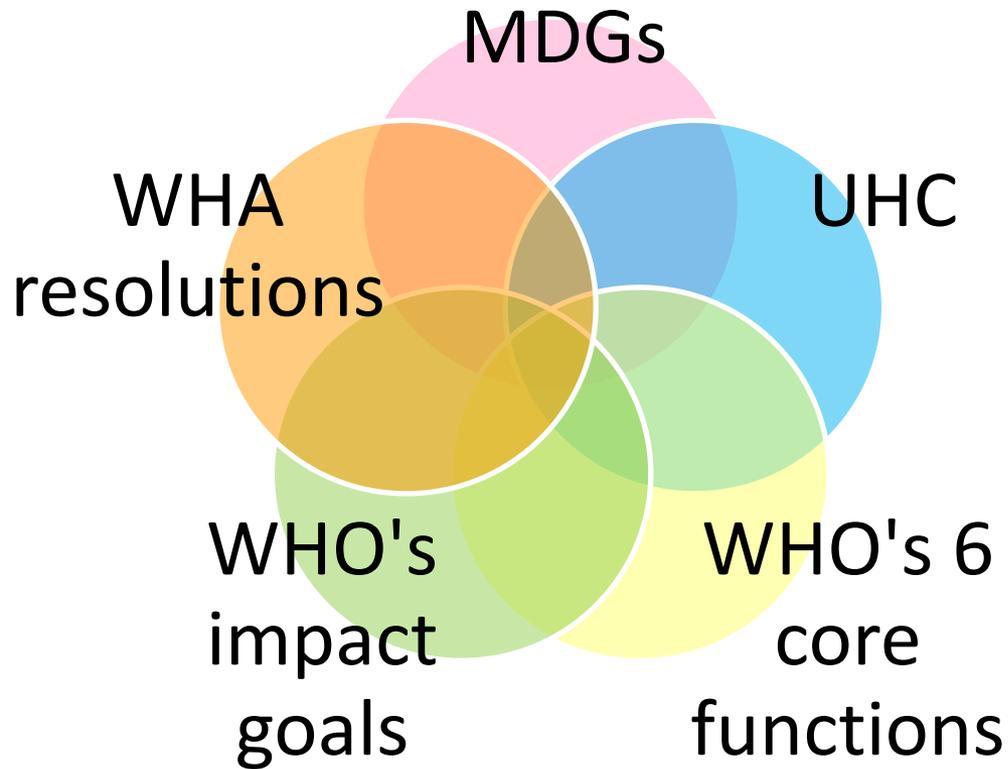
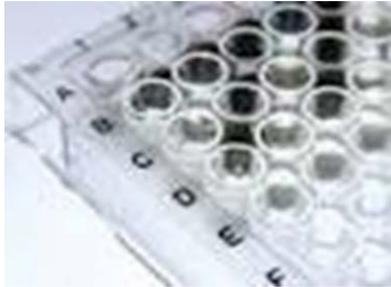
# The WHO prequalification of in vitro diagnostics programme

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# WHO's work in IVDs area: background



# Millennium development goals

The United Nations Millennium Development Goals are eight goals that all 191 UN Member States have agreed to try to achieve by the year 2015.

- 4. to reduce child mortality;
- 5. to improve maternal health;
- 6. to combat HIV/AIDS, malaria, and other diseases;



# Universal health coverage

Universal coverage is based on the **WHO constitution** of 1948 declaring health a fundamental human right and on the Health for All agenda set by the **Alma-Ata declaration** in 1978.

For a community or country to achieve universal health coverage, several factors must be in place, including:

Access to essential medicines and technologies to diagnose and treat medical problems.



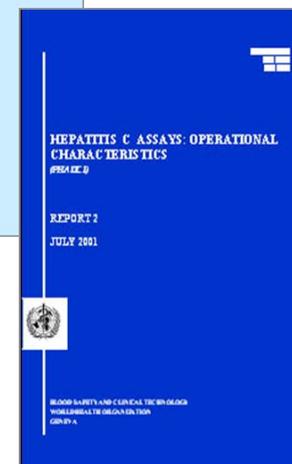
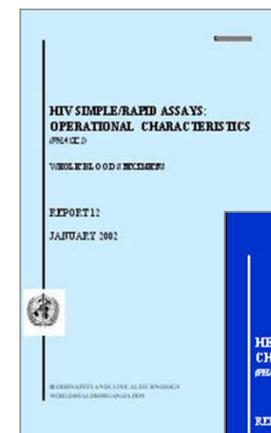
# Role of WHO prequalification

- > Facilitate access to safe, appropriate priority IVDs, medicines and vaccines
- > Support two of WHO's six core functions
  - > setting norms & standard/promoting their implementation
  - > providing technical support, catalyzing 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's role in IVDs QA

- > WHO has been assessing IVDs 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
  - > Alternatives to viral load started 2005
- > 2008: shift to PQ following medicines model



# Prequalification of in vitro diagnostics programme

- > Aims at promoting and facilitating **access** to safe, appropriate and affordable IVDs of good quality in an equitable manner
- > Undertakes a **comprehensive assessment** of individual IVDs through a standardized procedure aimed at determining if the product meets PQ requirements.
- > Requirements based on best international practice: ISO, GHTF/IMDRF guidance, CLSI etc.
- > Focus is placed on IVDs for priority diseases
- > Is coordinated through the department of Essential Medicines and Health Products, PQ Team



# PQ assessment findings as procurement driver

- > Assessment findings are used to provide **independent technical information** on safety, quality and performance of IVDs, principally to other United Nations (UN) agencies but also to WHO Member States and other interested organizations.
- > The PQ status, in conjunction with other procurement criteria, is used by UN agencies, WHO Member States and other interested organizations to **guide their procurement** of IVDs.



# Prequalification of in vitro diagnostics programme

- > Includes three components:
  - > Review of a product dossier;
  - > Performance evaluation, including operational characteristics; and
  - > Manufacturing site(s) inspection.
- > Looks into quality, safety and performance through dossier review, performance evaluation and inspection
  - > Dossier: safety and performance
  - > Performance evaluation: performance
  - > Inspections: quality



# Abbreviated PQ assessment

Where a stringent review took place PQ leverages review outcomes

Avoids duplication of efforts; focus on specific aspects

Only applies where same version of product is submitted to PQ or where difference is minimal

Full PQ assessment	Abbreviated PQ assessment
Dossier review	No dossier review but specific aspects reviewed during inspection
Performance Evaluation	Performance Evaluation
inspection	Abbreviated inspection including specific dossier aspects



# What does PQ do differently to GHTF/IMDRF

Requirements are based on the same set of standards – PQ is aligned with internationally accepted practice BUT

## **Assess products' regulatory versions intended for the global market**

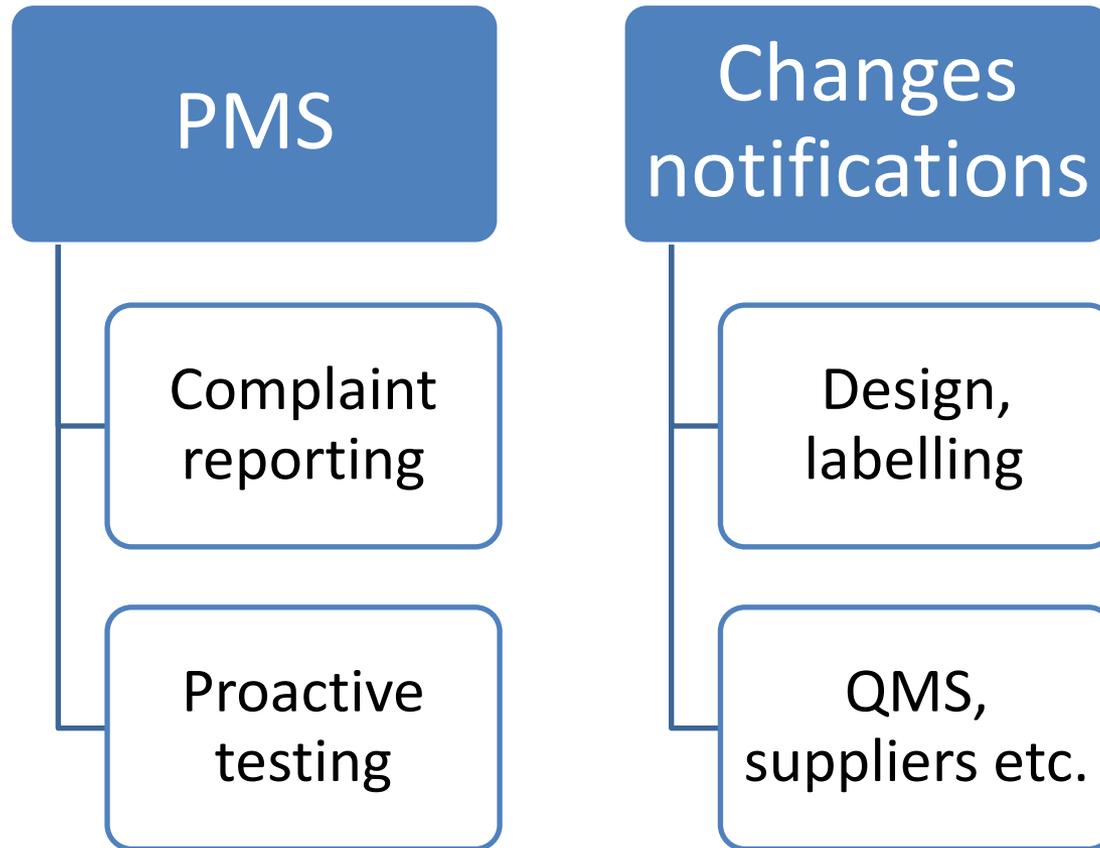
- Where a stringently reviewed versions exist, they are often not supplied to the global market – RoW versions differ from stringently assessed version in Mx site, QC, labelling, key suppliers, composition, intended use etc.

## **Review aspects of particular relevance for resource-limited settings**

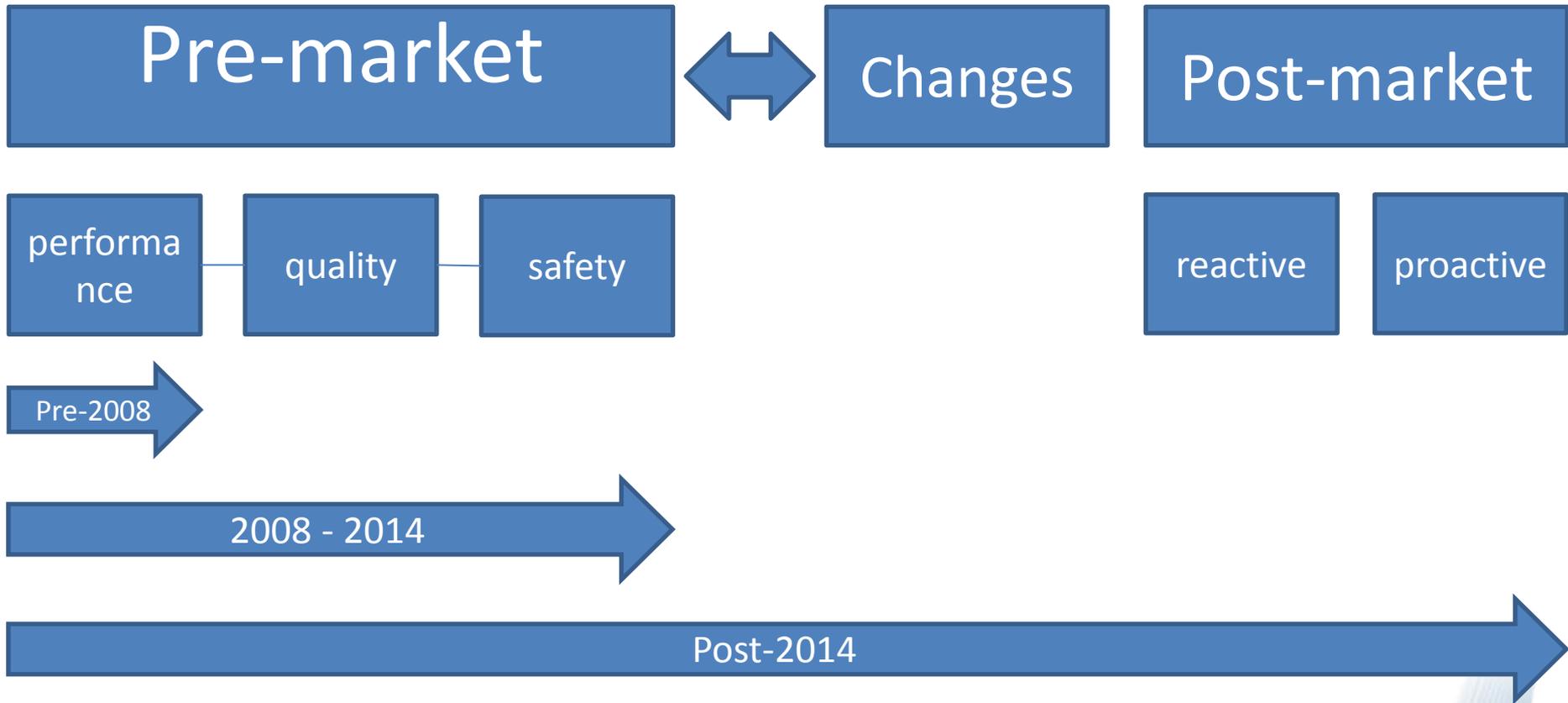
- Risk assessment, stability, flex studies, labelling, training and support network
- Take into account environment and user skills



# Post-prequalification phase



# PQ in a regulatory framework



Thank you

Any questions?

