WHO Prequalification of in vitro diagnostics- Updates

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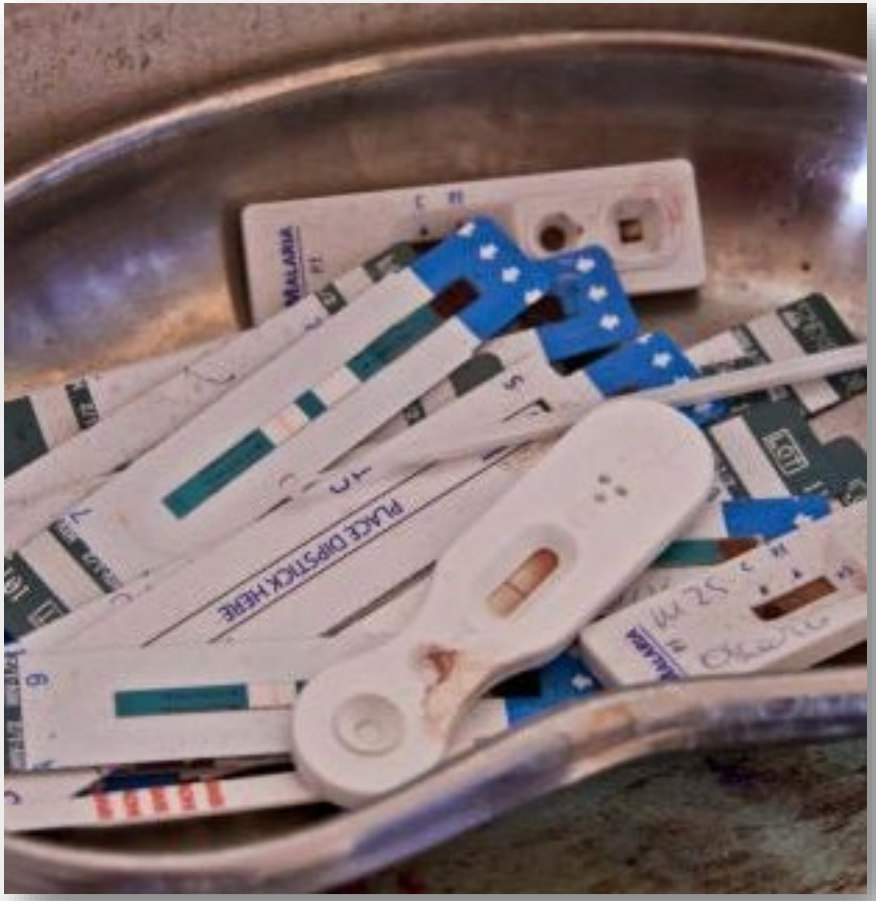
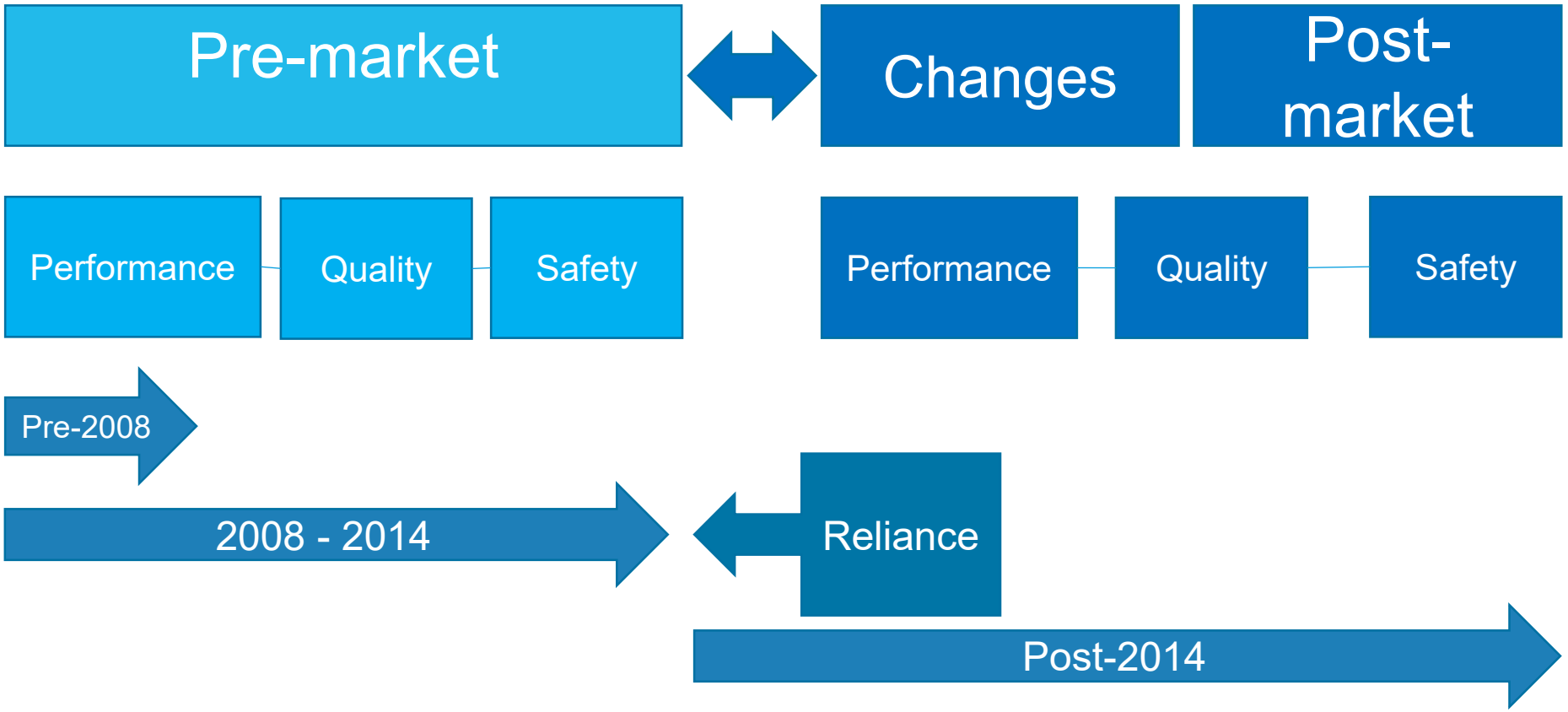
PQDx: aim, scope and impact



The findings of PQDx generate independent technical information on safety, quality and performance of IVDs, principally used by other UN agencies, WHO Member States and other interested organizations.

The PQDx 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.

WHO's response: PQ in a regulatory framework – product lifecycle approach



Updates on:

- Prequalification of IVDs
- CRP for IVDs
- Inspections updates.

PQDx IVD product dossiers – ToC format

World Health Organization

- WHO accepts PQ applications for: HIV, HCV, HBV, HPV, malaria, cholera, syphilis, CD4 and G6PD deficiency; EIA, RDT, NAT, etc.
  - Broad PQ product dossier requirements in “PQDx_18 Instructions for Complication of a Product Dossier”
  - Detailed product-specific requirements elaborated in Technical Specifications Series (e.g. TSS-1 HIV-1 RDTs; TSS-2 G6PD, etc)
- Dossiers are provided in, and reported against, **STED format**
- WHO PQ Diagnostic Assessments to implement **ToC format**:
  - Align with best practice
  - Provide platform for countries participating in Collaborative Registration Procedure (e.g. shareable assessment reports)

PQDx IVD product dossiers – ToC format

World Health Organization

Roadmap:

- Develop pilot ToC format dossier reports for two assessed products:
- Map existing STED assessment report onto new ToC format report template

Implementation of ToC format report template for each published TSS (elaborates product-specific requirements)

New product dossiers to be requested in ToC format

Revision of TSS to reflect ToC format

Transition period

PQDx Inspections

The evidence of manufacturer's compliance with the requirements of ISO13485:2016 and WHO TSS - obtained via:

- a WHO on-site inspection
- a desk-top assessment of a stringent review report (e.g. MDSAP report)

WHO inspections:

- Follow MDSAP audit model
- Follow N19 for grading of nonconformities
- Utilise MDSAP report format and NGE (Nonconformities Grading and Exchange) form.

PQDx Inspections

WHO is working on minimizing the duplication of audit effort

WHO participates as an observer in MDSAP activities

- Input was provided for the inclusion of WHO requirements into the next Audit Model
- The implementation postponed until the transition of all Canadian manufacturers is completed as planned in 2019

WHO reportable changes to prequalified male circumcision devices

World Health Organization

WHO published the final document in Q2 2019

- Guidance on how to manage and classify changes to a prequalified product

https://www.who.int/diagnostics_laboratory/male_circumcision/190701_reportable_changes_to_a_who_pq_mcd_pqmc_121_v1.pdf?ua=1

Electronic Prequalification System (e-PQS)

Bringing together all of PQ programmes* into one database

More efficient management of applications and improved platform to monitor and evaluate performance of WHO and manufacturers

Manufacturers will be required to complete forms online and upload required documentation

Expected to be launched in Q4 2019

*In Vitro Diagnostics, Male Circumcision Devices, Medicines, Vaccines and Vector control products

2018 Prequalification Guidance and specifications development

Finalized Technical Specification Series (TSS) and Technical Guidance Series (TGS) documents published in 2018

TGS-7	**Risk management for manufacturers of IVD**
TSS-5	**Rapid diagnostic tests used for surveillance and detection of an outbreak of cholera**
TSS-6	**Syphilis rapid diagnostic tests**
TSS-7	**Rapid diagnostic tests to detect hepatitis C antibody or antigen**
TSS-8	**Immunoassays to detect hepatitis C antibody and/or antigen**

2019 Planned Prequalification Guidance and Specifications development

TSS/TGS documents for public comment in 2019

TGS	**Use of biological reference materials in the development of IVDs**
TGS	**Use and validation of accessories**
TGS	**Precision and robustness**
TSS	**Immunoassays to detect HIV antibody and/or antigen**
TSS	**IVDs used for the qualitative and quantitative detection of hepatitis C by NAT**
TSS	**IVDs used for the quantitative detection of HIV-1, and for the qualitative detection of HIV-1 and HIV-2 by NAT**

Collaborative Registration Procedure for Medical Devices (including IVDs)

World Health Organization

- WHO Collaborative Registration Procedure (CRP) is expanding to involve Medical Devices (including IVDs);
- Pilot CRP for accelerated registration of Prequalified IVDs is being organized for countries in Sub-Saharan Africa;
- Specific expected outcomes for the pilot:

  a) Registration of 2 prequalified IVDs in at least 3 of the 5 participating countries following CRP workshop within the recommended timeline;

  b) A revised Procedure based on lessons learnt from the pilot.

Regulation of medical devices including IVDs in the East African Community

In 2016 the EAC Sectoral Council of Ministers of Health approved the implementation of EAC project on strengthening and harmonization of regulations for medical devices (including in-vitro diagnostics) – as part of the EAC Medicines Regulatory Harmonization Project;

The EAC Partner States NMRAs are expected to take into consideration the WHO Model for successful introduction of medical devices and IVDs regulations in their regulatory systems;

With the support of WHO EAC Secretariat and the EAC Partner States NMRAs drafted the EAC Model Framework and corresponding harmonized regulatory requirements;

Once finalized, endorsed and successfully implemented this framework would be recommended for adoption and implementation by other African Regional Economic Communities – in the context of AMRH.

Towards Standardized international nomenclature of medical devices

Due to the diversity and lack of harmonized nomenclature systems in the WHO member states,

- WHO launched a 1st working version during the 4th WHO Global Forum on Medical Devices, in India. December 2018.
- Principles of this system:
  - WHO governance
  - Transparent assignation of codes, definitions and names
  - Freely available for all stakeholders
  - Hierarchical and one code per type of device. Based in ICD11 platform.
  - WHO is open to cooperation and proposals

More information at:
https://www.who.int/medical_devices/priority/mde_nomenclature/en/index4.html

Nomenclature of medical devices is an agenda item of the WHO Executive Board 145 in May 2019.

Outcomes of the 4th WHO Global Forum on Medical devices

World Health Organization

Venue: India, 13 to 15 December, 2018

1249 participants from 92 countries

Priority areas of work for 2019:

- WHO Essential in vitro diagnostic List https://www.who.int/medical_devices/diagnostics/selection_in-vitro/en/
- Nomenclature of medical devices
- Regulations of medical devices
- Technical specifications for procurement

More information and presentations: https://www.who.int/medical_devices/global_forum/4th_gfmd/en/

Thank you

World Health Organization

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