WHO Update

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Updates on:

- Prequalification of IVDs
- CRP for IVDs and MDs regulations in EAC
- MDs nomenclature

PQDx IVD product dossiers – ToC format

- 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

- 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

- WHO will publish the final document in Q2 2019
  - Guidance on how to manage and classify changes to a prequalified product

https://www.who.int/diagnostics_laboratory/180627_draft_mcd_guidance_for_comments_v01.4.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**

- As result, two new IVD product streams added to the WHO Prequalification assessment programme
- In addition, published two draft TSS for public comment

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 planned 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**

- Documents developed based on international recognized best practice and standards, and using a consultative process during development to ensure acceptance by manufacturers and to confirm they are practical to implement

Collaborative Registration Procedure for Medical Devices (including IVDs)

- 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

- 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