IMDRF International Medical Device Regulators Forum

Update from the World Health Organization

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1. WHO Emergency Use Listing Procedure for IVDs

WHO EUL for IVDs

IVDs eligible for EUL submission:

- Assays for the detection of SARS-CoV-2 nucleic acid;
- Rapid diagnostic tests and enzyme immunoassays for the detection of IgM/IgG to SARS-CoV-2; and
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens.

WHO instructions and requirements for NAT and Ag detection RDTs and IVDs detecting antibodies to SARS-CoV-2 virus.

Manufacturers who are interested in an EUL contact diagnostics@who.int to arrange a pre-submission call

https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open

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2. WHO Prequalification of IVDs

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PQDx: New abridged assessment procedure implementation in Q1 2021

Manufacturers leveraging abridged PQ assessments have provided comments on the previous procedure through their associations

- Avoiding site inspections where MDSAP reports are available
- Requesting abridged product dossier to assess data from technical files
- Consider other IMDRF jurisdictions with recognized assessments

New guidance developed based on comments received during consultation period

New procedure launched in Jan 2021

- Abridged dossier with focused sections: replaces reviews on-site
- Site inspections leveraging MDSAP reports
- No changes to performance evaluation
- Addition of HSA to the list of recognized reviews

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PQDx: implementation of ToC dossier format extended until 2022

A new, ToC-specific version of the WHO publication "PQDx_018 Instructions for Compilation of a Product Dossier" is available at our website:

- https://extranet.who.int/pqweb/sites/default/files/documents/200324_draft_Instruction_for_compilation_of_a_product_dossier_pqdx_018_v4_toc_0.pdf

These instructions are open for public comment over the transition period

Any comments may be directed to diagnostics@who.int

In light of the Covid-19 pandemic, the transition period is extended to end of 2021.

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PQDx: Update on inspections

Inspections:

- Most onsite inspections postponed
- Desk assessments performed
- SOP for remote assessment developed

Training and workshops:

- Prequalification / Collaborative Registration Procedure for African states
- Joint UNICEF – UNFPA – WHO Meeting with Manufacturers and Suppliers

Future plans:

- Accelerate deployment of remote or hybrid assessments
- Initiate post-market surveillance inspection

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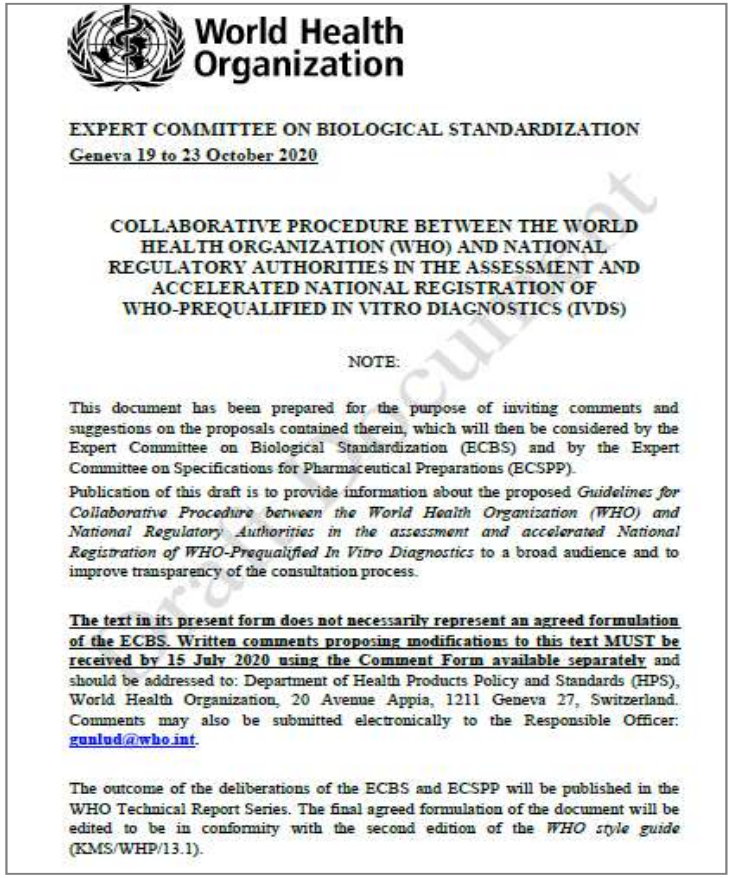
3. Regulatory strengthening

Collaborative registration procedure



World Health Organization

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva 19 to 23 October 2020

COLLABORATIVE PROCEDURE BETWEEN THE WORLD HEALTH ORGANIZATION (WHO) AND NATIONAL REGULATORY AUTHORITIES IN THE ASSESSMENT AND ACCELERATED NATIONAL REGISTRATION OF WHO-PREQUALIFIED IN VITRO DIAGNOSTICS (IVDS)

NOTE:

This document has been prepared for the purpose of inviting comments and suggestions on the proposals contained therein, which will then be considered by the Expert Committee on Biological Standardization (ECBS) and by the Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP).

Publication of this draft is to provide information about the proposed *Guidelines for Collaborative Procedure between the World Health Organization (WHO) and National Regulatory Authorities in the assessment and accelerated National Registration of WHO-Prequalified In Vitro Diagnostics* to a broad audience and to improve transparency of the consultation process.

The text in its present form does not necessarily represent an agreed formulation of the ECBS. Written comments proposing modifications to this text MUST be received by 15 July 2020 using the Comment Form available separately and should be addressed to: Department of Health Products Policy and Standards (HPS), World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland. Comments may also be submitted electronically to the Responsible Officer: gunlud@who.int.

The outcome of the deliberations of the ECBS and ECSPP will be published in the WHO Technical Report Series. The final agreed formulation of the document will be edited to be in conformity with the second edition of the *WHO style guide* (KMS/WHP/13.1).

Guidance document was adopted by the 72nd ECBS which took place in October 2020 and is available at *https://www.who.int/publications/m/item/collaborative-procedure-between-the-who-and-nra-s-in-the-assessment-and-accelerated-national-registration-of-who-prequalified-ivd-s-annex4*

Roll out is planned from May 2021 after the guidance is published in the WHO Technical Report Series during the WHA.

Three CRP workshops on HIV self test were conducted in Uganda, Cameron and Mozambique to facilitate registration of IVDs.

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Regional Initiatives for medical devices including IVDs regulation

WHO is supporting the Africa Medicines Regulatory Harmonization Initiative through the African Medical Devices Forum (AMDF) Technical committee to harmonize regulatory requirements and strengthen regulation of medical devices including in vitro diagnostics in Africa. Some of the activities supported by WHO include :

•Monthly update of the list of COVID-19 IVDs and other medical devices which have been listed by WHO PQ and other matured NRAs including IMDRF MS;

•Development of guidance documents based on IMDRF recommendations;

•Development of training materials for regulatory experts;

•Conduct webinars and meetings and

•Secretariat role in collaboration with AUDA-NEPAD.

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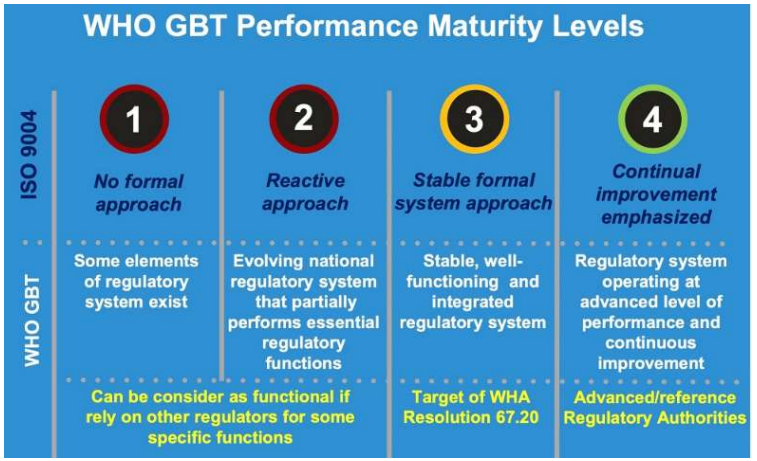
WHO Global Benchmarking Tool Plus medical devices

WG members: WHO, Medical devices and IVDs regulators and laboratory experts and other MDs experts

Discussion : 1 September 2020 to 18 January 2021.

Status: Final review and consultation within WHO and experts until end on March 2021.

Piloting of the WHO GBT plus medical devices tool is planned on Q2 of 2021



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4. Safety of medical devices

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Safety of medical devices

Updated WHO guidance on post-market surveillance and market surveillance for medical devices including IVDs, launched Nov 2020

WHO guidance on use of Artificial Intelligence-based medical devices, use case for cervical cancer screening and diagnosis

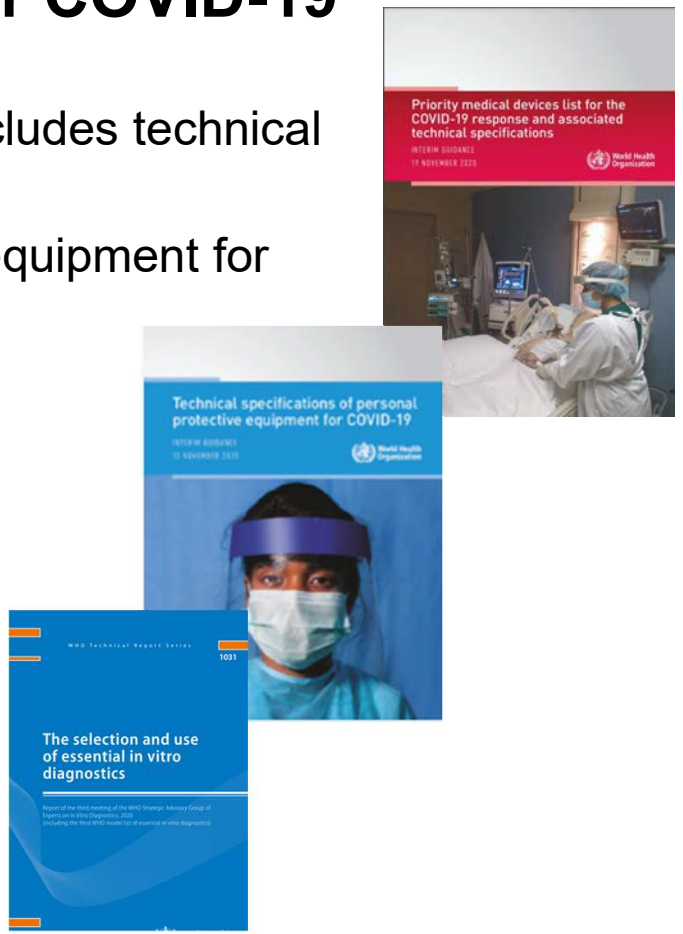
Use of blockchain to enable better post-market surveillance of IVDs – won internal WHO innovation challenge, concept paper on-going

https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1

WHO Medical devices, PPE and IVDs for COVID-19

- The list of Priority medical devices for COVID-19, includes technical specifications for 100 medical devices. (Nov 2020)
- The technical specifications for personal protective equipment for COVID-19 (Nov 2020)
- This specifications have allowed procurement of
  - $1 billion of essential Covid19 supplies for 181 countries
  - 720 million units of PPE were supplied to 163 countries

- The 3rd edition of Essential in vitro diagnostic list,
  - Includes 200 tests including 2 COVID-19. (January 2021)



Ref: https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1
https://www.who.int/health-topics/medical-devices#tab=tab_1

Nomenclature for Medical devices

- 23rd of January 2021, discussion on nomenclature took place in Executive Board of WHO.
  - 16 Members States (MS) gave a statement.
  - Requests: To have a MS information session to provide more information on the analysis.
- Next steps: A MS information session proposed to take place in April and September. Dates to be confirmed.

https://www.who.int/teams/health-product-and-policy-standards/access-to-assistive-technology-medical-devices/medical-devices/nomenclature
https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_13-en.pdf

Thank you