IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

11:50 – 12:05

World Health Organization – Official observer

Irena Prat

Team Lead, In vitro diagnostics assessment, Prequalification Unit

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Update from the World Health Organization

Irena Prat, Team Lead

World Health Organization

28 March 2023

Overview

Regulatory system strengthening activities

Prequalification and EUL of IVDs

Nomenclature and EDL

Revision of the WHO Global Model Regulatory Framework (GMRF) for medical devices

New Table of contents

Chapter 1. Introduction

Chapter 2. Definition, classification, essential principles, and conformity assessment of medical devices

Chapter 3. Enabling conditions for effective regulation of medical devices including IVDs

Chapter 4. Establishing a stepwise approach to regulating medical devices

Chapter 5. Regulatory pathways *New*

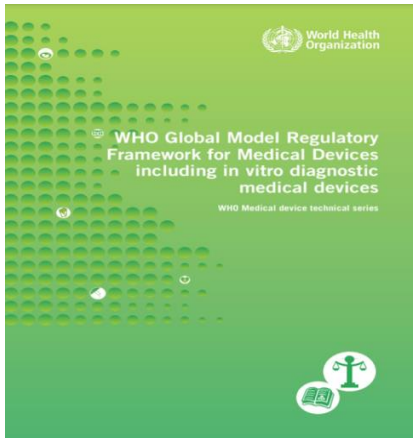
Chapter 6. Additional topics

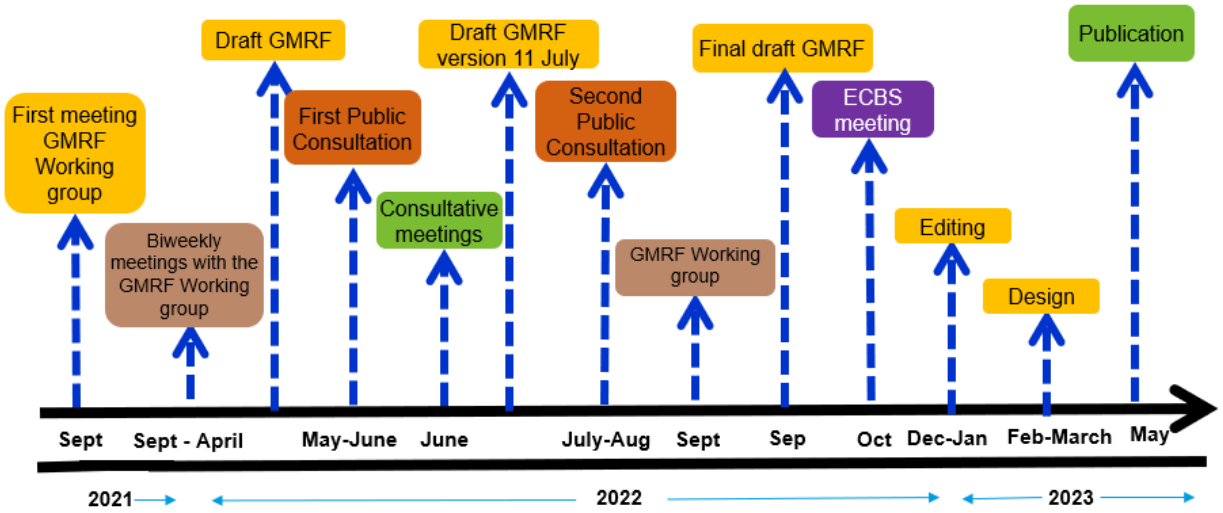
Chapter 7. Implementation *New*

**** Chapters have been expanded from 5 chapters in the 2017 version to 7 chapters in the revised version***

WHO GMRF for medical devices including in vitro diagnostics was successfully revised and endorsed during the 76th meeting of the WHO Expert Committee on Biological Standardization (ECBS) held from 24 to 28 October 2022

Final editing and design of the revised Model and publishing in May 2023





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Technical support and reliance

Support to AMRH Technical Committee

In 2022, development of a five-years AMDF Strategic Plan & four (4) guidelines

- 4 guidelines are planned for development in 2023

Good Regulatory Practices (GRP) and Good Reliance Practices (GRelP)

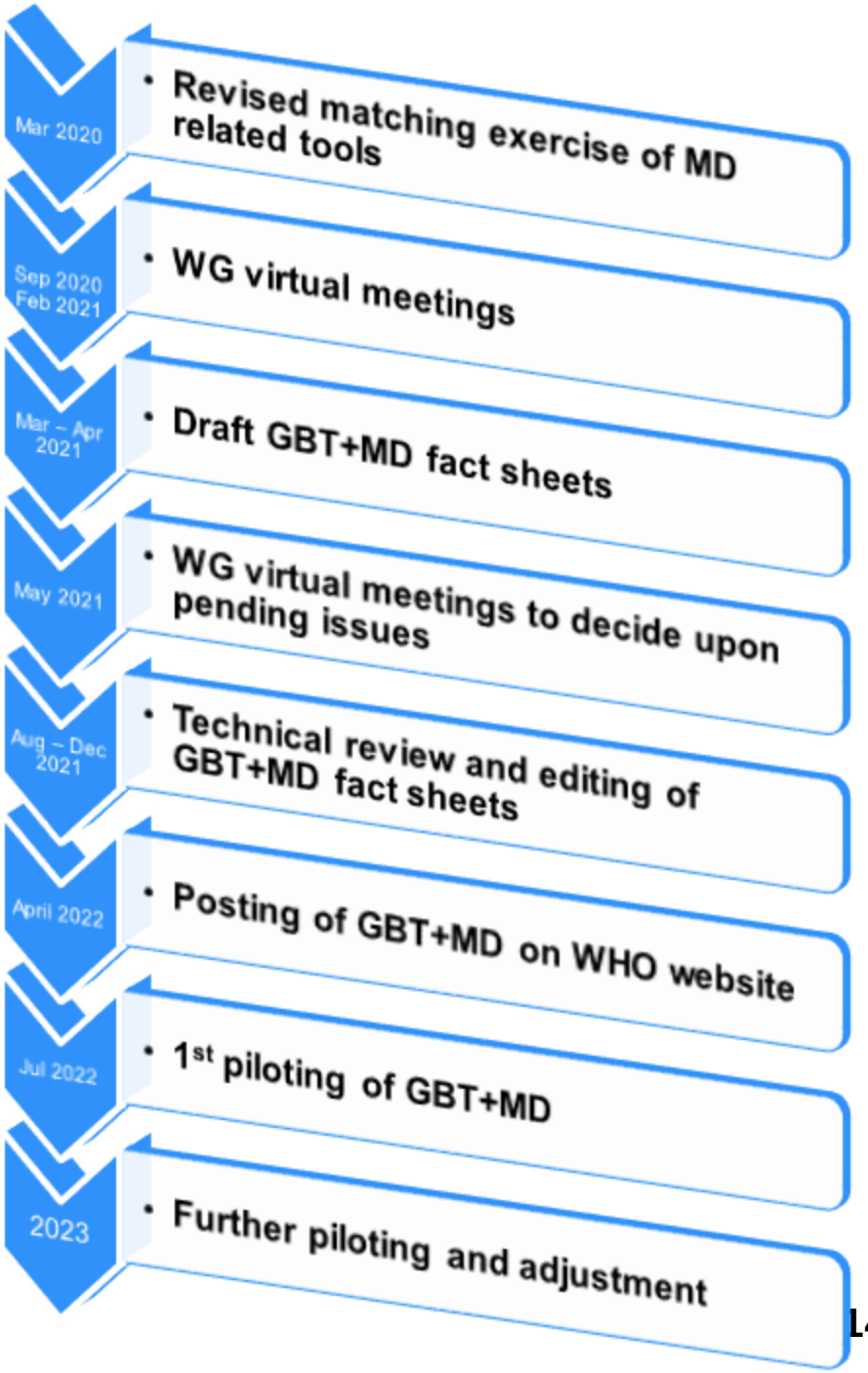
- Promoting adoption of the principles and concepts in both GRP and GRel documents
- e-learning Module on GRelP on OPEN WHO https://openwho.org/courses/good-reliance-practices

Promoting Collaborative Registration Procedure (CRP) for IVDs

- Over 20 advocacy workshops/meetings including 10th annual CRP meeting in Dec 2022
- Increased NRAs' interest to sign to CRP & IVDs registered e.g., from 16 in 2021 to 26 in March 2023

Global Benchmarking Tool (GBT)

- GBT represents the primary means by which the WHO **objectively evaluates regulatory systems** (*Resolution WHA 67.20*)
- GBT (medicines & Vaccines) introduced in 2016 and revised in 2018
- GBT **replaces all tools previously used** by WHO, representing the first truly 'global' tool
- Nov. 2019, **GBT+Blood** (whole blood, blood components and plasma derived blood products) integrated into the GBT
- April 2022: **GBT+Medical Devices** including IVDs integrated into the GBT (link)



Development of GBT+MD

GBT+MD developed in **consultation with regulators (including global ad regional networks), WHO regional offices**

- Several virtual meetings with over **50 participants** from **20 countries representing all six WHO regions**

GBT+MD **piloted** for the first time in **July 2022**

- confirmed its value in benchmarking of medical devices regulatory systems in LMICs
- Revealed some **areas** which **need further improvement** particularly with respect to **terms** and **terminology** and the role of **conformity assessment bodies (CAB)**
- Lessons will help further refine the tool

Further piloting planned in **2023** in order to get feedback for **refining and adjusting** the tool

Post-market surveillance and market surveillance

Supporting WHO Member States

- Highlighting reliance/recognition for review of investigation reports and field safety corrective actions
- Assessing need for a global database on field safety notices for medical devices
  - FSN are publicly available but not very accessible

WHO e-learning, launched 9 March 2023

- Basics of how to respond to substandard/falsified medical devices

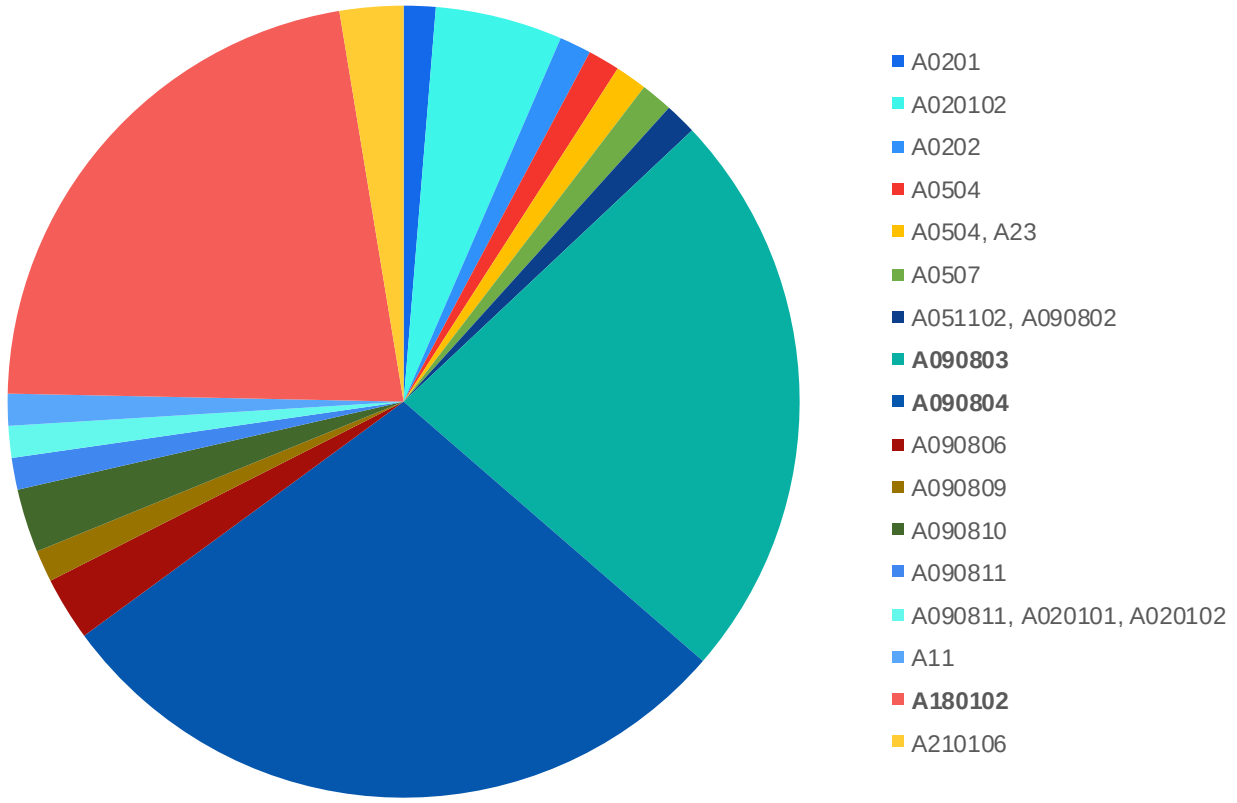
WHO Global Surveillance and Monitoring System

Substandard and falsified IVDs

- In last 12 months, 77 incidents reported to WHO
  - 78% reported by manufacturers

AER terminology used

- False positive (28.4%)
- False negative (25.4%)
- Contaminated (22.1%)



WHO Prequalification: Eligibility expansion and new guidance for manufacturers

PQ technical specifications finalized and published for IVDs detecting **Hepatitis B virus** (RDTs and EIA for HBsAg and HBV NAT)

- January 2023, HBV NAT assays eligible for PQ assessment

Draft PQ technical specifications for **HbA1c** POC IVDs published for public comment end 2022

Plan to publish draft PQ technical specifications for **blood glucose monitors** in Q1/2 2022, **haemoglobin POC** analyzers, and updated requirements for **Malaria** RDTs in Q2 2022.

EUL assessment for **SARS-CoV-2** detection IVDs likely to transition to PQ assessment (timeline and scope to be determined)

PQDx IVD product dossiers and inspections

WHO PQ has implemented the **ToC format for dossiers** and review reports

- As of 2023 Manufacturers are expected to provide product dossiers in ToC format only
- Dossier requirements, and dossier review documents have been updated to reflect ToC
- Training for assessors, and guidance for manufacturers will be provided

Inspections in 2022:

- Inspections
  - 13 Onsite
  - 1 Desk assessment
- Emergency use listing
  - 12 new applications (1 rejected)
  - 12 renewals (1 delisted)
- Training and workshops
  - Collaborative registration procedure for IVDs
  - EUL workshop for Turkey
- Guidance
  - Guidelines review committee
  - Artificial intelligence Medical Devices IMDRF WG

WHO EUL IVD and related projects

- Over 200 EUL applications received

ECBS 2022: **1st WHO International Standard for SARS-CoV-2 antigen (21/368)** was established
https://www.who.int/publications/m/item/who-bs-2022.2426-rev

- lyophilized preparation of formaldehyde-inactivated cell culture-grown SARS-CoV-2 Omicron BA.1 subvariant
- assigned unitage of 5000 IU/ampoule
- availability: https://www.nibsc.org/

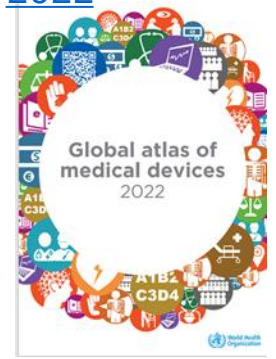
Independent Performance Evaluation of SARS-COV-2 Ag RDTs

- supports WHO EUL (applicable to listed products and products under assessment)
- collaboration PATH, FIND & WHO
- focus on analytical performance
- start date: Q1/Q2 2023

* cancelled in Feb 2023

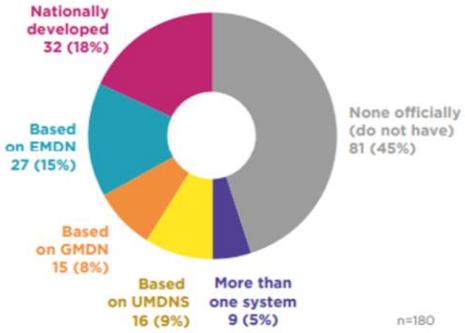
WHA72(25), Standardization of medical devices nomenclature, International classification, coding and nomenclature of medical devices Decided to request the WHO Director General

Global Atlas Medical Devices 2022



To integrate available information related to medical devices, including terms, codes, and definitions, in the web-based database and clearinghouse established in line with resolution WHA60.29 (2007) and now available as the Medical Devices Information System (MEDEVIS);

and to link this to other WHO platforms, such as the International Classification of Diseases, (ICD-11) to serve as a reference to stakeholders and Member States



Relation terms and codes EMDN - GMDN Dec- July 2023

Webinars and consultations

MOUs with nomenclature agencies

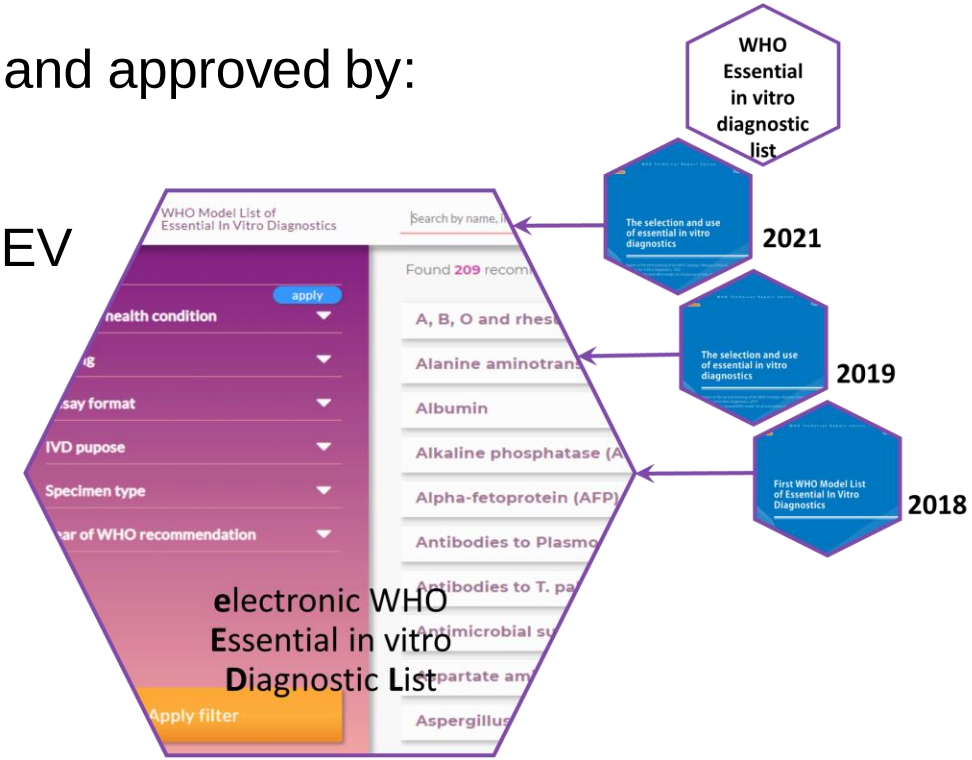
Q2-Q3

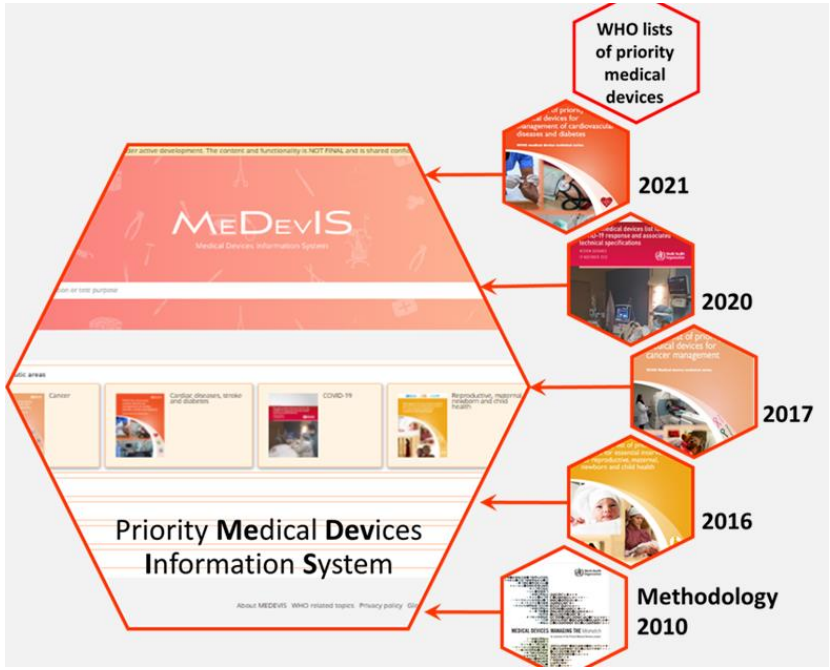
Publication and work on updates Q4

Update of WHO Priority Medical devices list and Essential in vitro diagnostics list: both in electronic platforms

Evidence based and approved by:

- SAGE IVD
- STAG MEDEV





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Thank you/Questions

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