Regulatory Update from the World Health Organization

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IMDRF International Medical Device Regulators Forum

WHO Global Benchmarking Tool (GBT) + MD

Piloting and Refinement

- **Between March 2020 & April 2022,** GBT+MD integrated into the GBT and published
- **Piloted in July 2022 (Kenya) and in September 2023 (Singapore, with participation of experts from Republic of Korea)**
- **Pilot revealed some areas which need further improvement particularly with respect to:**
  - ✓ Full **alignment** with latest version of the WHO Global **Model Regulatory Framework** for medical devices e.g., discouragement of pre-approval lab testing (LT)
  - ✓ **Terms** and **terminology**
  - ✓ The role of **third parties** e.g., conformity assessment bodies [CAB]/notification bodies [NB], accredited laboratories and accreditation bodies [in case of LT function])
  - ✓ **Merging** of market control (**MC**) and vigilance (**VL**) functions
- **Working Group (WG) discussions between December 2023 and February 2024**
  - ✓ Discussed and agreed on areas of amendment based on the findings from the pilots, thanks to contribution from IMDRF members, RHIs and other regulators
  - ✓ **Next steps**
    - WHO to work on the suggested amendments of the fact sheets
    - Finalization and publication of updated GBT+MD before end of 2024

Collaborative Registration Procedure for Prequalified IVDs and technical support to regulators

Collaborative Registration Procedure (CRP):

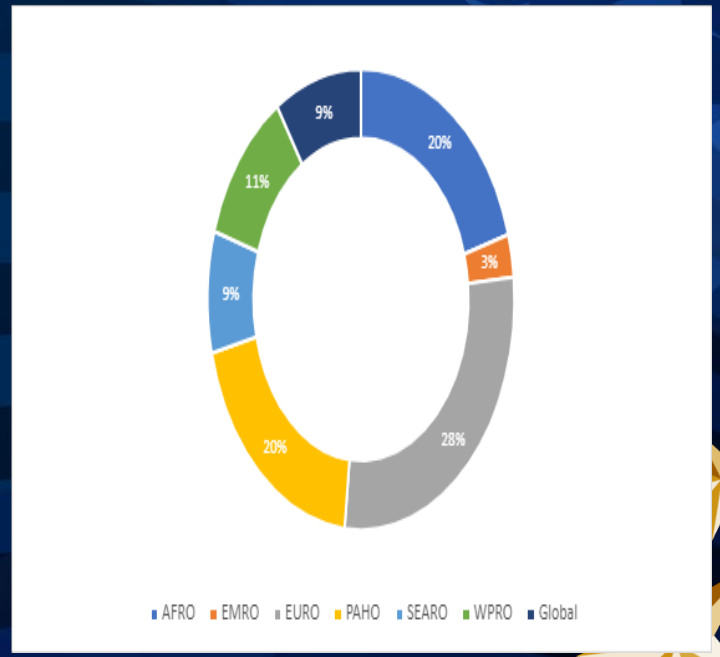
- CRP advocacy workshops for Francophone countries in Africa, September 2023 in Cotonou, Benin
- 11th CRP annual meeting, in Dec 2023, Doha, Qatar, attended by over 400 participants (Regulators, Industry and Partners) – including 72 from medical devices world (20 in person, 52 online)
- **Current status**
  - 31 national regulatory authorities joined CRP since 2020
  - 20 assays registered in countries through CRP with average time of 48 days (target time: 90 days)
- CRP Advocacy workshop planned for July 2024 and 12th Annual meeting in November 2024

Technical support:

- Continue to provide technical and Secretariat support to AMDF in collaboration with AUDA NEPAD
- 12 regulators from 10 African countries trained on assessment of medical devices technical files (MCH devices) & hosted by Tanzania Medicines and Medical Devices Authority (TMDA)
  - ✓ In collaboration with MSH/MTaPs, 30th Oct – 03 November 2023
- Online basic training on fundamentals for regulating medical devices including IVDs
- WHO is currently developing training materials for assessment of IVDs technical files

Global Surveillance and Monitoring System for substandard and falsified medical products

- 459 IVD incidents were reported to WHO (2012 - 2023
  - ✓ 150 incidents in 2023 alone
  - ✓ All were WHO recommended IVDs
  - ✓ Predominantly reported by manufacturers (76%)
  - ✓ 40.7% incidents were for HIV-related IVDs
  - ✓ 7.6% incidents were for malaria IVDs
  - ✓ 48% incidents reported from Europe or Americas region
  - ✓ Under reporting from other regions
- Strengthening market surveillance is key
- IMDRF coding for product problem, investigation type/findings/conclusion
  - ✓ Implemented in WHO Global Surveillance and Monitoring System (GSMS)



WHO Prequalification: scope expansion

- **Transition of SARS-CoV-2 NAT and Ag RDTs from EUL to PQ**
  - Technical Specifications TSS-20 and TSS-21 have been published
- **NCDs: glucose meters and test strips, and HbA1c**

Expansion plan for 2024:

- Hb PoC
- HPV self-collection
- Syphilis ST
- TB-LAM

Expansion plan for 2025:

- STIs (CT and NG)
- TB NGS

WHO Prequalification: new operating model and planned revisions

- **4 pilot Assessment Sessions for IVDs**
  - 31 technical experts and participants from 10 different National Regulatory Authorities
  - New PQ submissions and change requests assessment
- **In 2024, further 6 assessment sessions are planned to complement the PQT-IVD team's overall assessment process and support the timely delivery of IVD assessments**
- **A revised abridged assessment procedure planned in 2024**

Expert review panel for IVDs

- **Past focus on HIV, malaria, HCV and TB**
- **Risk-based mechanism including a desktop review of a technical file and QMS documentation**
- **Expansion to non-traditional products**
  - NTDs
  - VPDs
  - Soon for dengue

Decision approved by World Health Assembly, 28th May 2022. Standardization of medical devices nomenclature, WHA75(25)

Member States request to the Director General:

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;

- **to submit a substantive report on progress made in implementing this decision to the Executive Board at its 152nd session in January 2023, and its 156th session in January 2025**

WHO Member States information session on 5th March, 2024 on status of work and proposal for next steps.

, https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature

Medical Devices Nomenclature systems and WHO collaboration (February 2024)

European Medical Devices Nomenclature (EMDN)	Global Medical Devices Nomenclature (GMDN),	Universal Medical Devices Nomenclature System (UMNDS),	The United Nations Standard Products and Services Codes (UNSPSC),
○ Last update September 2021. ○ ongoing public consultation until March 2024. ○ Has free access of information for everyone. ○ Governed by MDCG. ○ Anyone can comment.	○ Continuous updates ○ About 25,000 codes ○ Requires membership and the system and accepts licence. ○ Free for some, including governments and public health providers.	• Monthly updates. • About 43,000 terms • Requires that user registers in their system and accepts licence. • Not free • Mostly used in hospitals for health technology management	• includes medical devices plus other multiple types of products and services. • Mostly used for procurement. • UNGM.
WHO-EMDN	WHO- GMDN	WHO- UMDNS	WHO- UNSPSC
• Codes and terms already used in all WHO MeDevIS data since 2023. •https://medevis.who-healthtechnologies.org/	• Inclusion of codes, terms and definitions in WHO MEDEVIS (tests in 2024) • Approval for WHO open access, using Creative Commons non commercial licence.	• In pause. • ECRI still does not have a publicly available nomenclature system	• WHO secretariat will contact in Q3. 2024. • They are interested.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