IMDRF International Medical Device Regulators Forum | 26th Session

Update from the World Health Organization

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World Health Organization

Regulatory system strengthening

SEATTLE WASHINGTON
SEA KING COUNTY "The Emerald City" The City of Flowers

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Development of GBT+MD (2020 – 2024) & Next steps

- **Following piloting in Kenya and Singapore (with participation of MFDS, Republic of Korea**
  - ✓Working Group (WG) discussions in December 2023 and February 2024
    - ➢agreed on areas of amendment based on the findings from the pilots
    - ➢alignment with the revised Global Model Regulatory Framework (GMRF)
- **<u>What are the next steps?</u>**
  - ✓ongoing amendments and language editing of the tool
  - ✓WG meeting in Sept and adopt final version of the GBT+MD
  - ✓publication and computerization
  - ✓implemented along with the GMRF – several countries expressed interest
  - ✓**<u>In the future:</u>** Revision of WLA Policy to integrate MDs, including IVDs

Collaborative registration Procedure for IVDs

- **Status**
  - ✓ 33 national regulatory authorities signed agreement to participate CRP - IVDs
  - ✓ 43 products registered in countries through CRP with average time of 48 days (within 90 days)

- **Workshops/meetings**
  - ✓ CRP Advocacy workshop in Kigali, Rwanda conducted in July 2024
  - ✓ CRP 12th Annual meeting planned for November 2024, Jakarta, Indonesia
- **Support NRAs**
  - ✓ Continue supporting the implementation of CRP through WHO RO and WHO CO
- **Review and update of Good Practices of NRAs in implementing CRP for medical products**
  - Draft guidance reviewed to include aspects of CRP for IVDs
  - Draft document under public consultation

Technical support African Medical Devices Forum (AMDF)

- **Supporting AMDF reforms to MDA-TC under the AMRH programme**
  - To support operationalization of the AMA, AMRH is planning to establish medical devices assessment technical committee (MDA-TC)
    - ✓ MDA – TC will assess priority medical devices and in-vitro-diagnostics at continental level
    - ✓ MDA -TC also will facilitate harmonization of requirements and standards for assessments, registration and marketing authorization activities at REC and NRA levels in Africa
    - ✓ Concept note finalized and Terms of reference on AMDF TC reform updated
- **Four AMDF guidelines finalized**
  - ✓ Emergency Use Authorization (EUA), Labelling, Registration and listing and Field Safety Corrective Action (FSCA) finalized by AMDF TC
    - Pending approval by the AMRH Steering Committee, followed by dissemination
- **Technical support**
  - ✓ Continue to provide technical and Secretariat support to AMDF in collaboration with AUDA-NEPAD
  - ✓ WHO training materials for assessment of IVDs technical files under final stages of preparation
    - Pilot workshop planned for Q1 2025

Monitoring substandard/falsified medical products

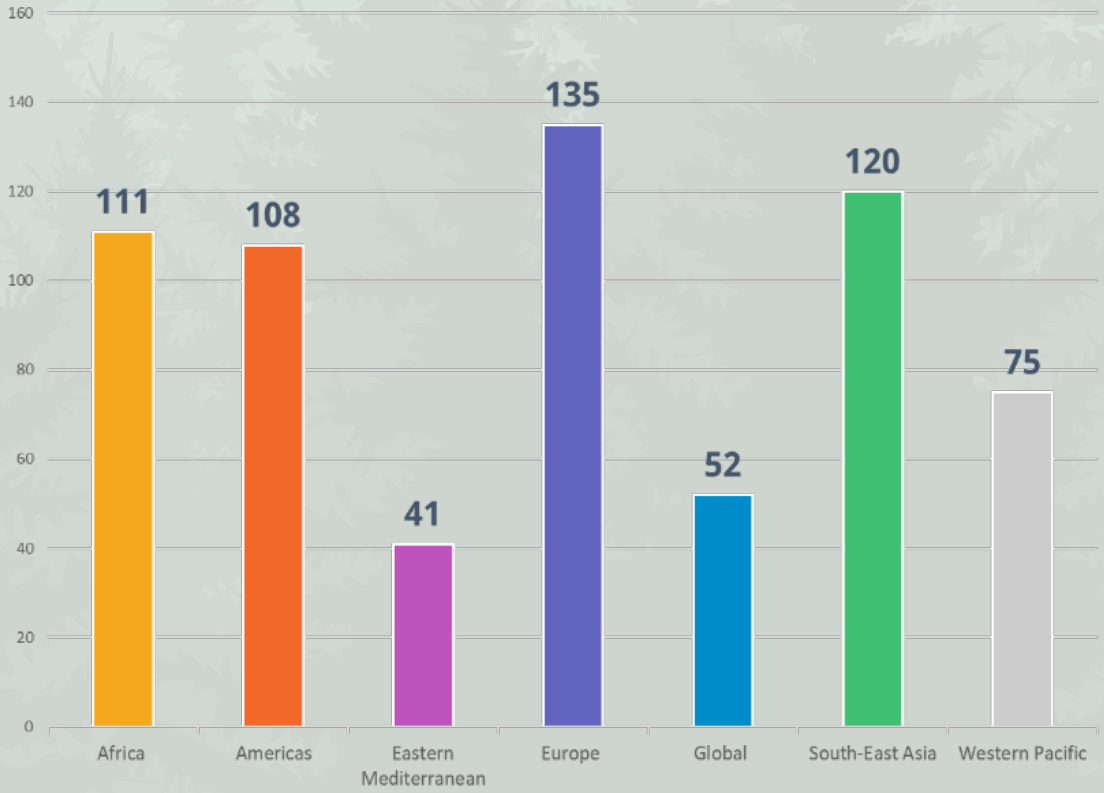
Global Surveillance and Monitoring System for substandard/falsified medical products

- Re-designing WHO's GSMS reporting portal for manufacturers to directly input incidents
  - Avoiding re-data entry, increased efficiency

One-stop searchable shop for IVD safety information

- Planning to automatically collate all field safety notices for IVDs recommended by WHO
  - Using WHO's Epidemic Intelligence from Open Sources (EIOS) system

WHO regions where IVD incidents occurred 2014-2024



Data Extracted 5 July 2024

WHO Prequalification of in vitro diagnostics

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Assessments of IVDs

1. Prequalification:

- PQ listing of the first HCV self-test

  Three assessment sessions held in first half 2024 to review product dossiers and change requests
  - Implemented to support efficient and standardized review of manufacturer's information
  - 42 subject matter experts from 22 different countries spanning all six of the WHO regions
- A further 3 assessment sessions are scheduled for second half of the year
  - First applications for Blood Glucose Monitoring Systems expected to undergo review

2. Expert Review Panel:

- Risk-based mechanism requiring a desktop review of a technical file and QMS documentation
- Ongoing focus on HIV, malaria, syphilis, HCV and TB
- Launch of pilot rounds for emerging needs

  NTDs: Visceral Leishmania/Lymphatic Filariasis IVDs

  VPDs: Meningitis

  Dengue

WHO Prequalification: Outreach

- IVD prequalification webinar series has been initiated
  - Information presented by members of PQ team followed by a Q&A session
    - Product dossier assessment
    - IVD PQ for new applicants
    - Technical specifications for HIV RDTs
  - Links to webinar recordings are available on PQ IVD website
  - Upcoming webinars will include change request assessment and TSS for TB LAM diagnostic tests
- Workshop for African manufacturers of HIV RDTs: *From QA to procurement* held in Kigali, Rwanda, 1-3 July.
  - 22 Manufacturers from 12 African countries participated in the workshop
  - Presentations from the Africa CDC, AUDA-NEPAD, FIND, Global Fund, PATH, Unitaid, PEPFAR/USAID and the World Health Organization (WHO)
  - Challenges to manufacturing in Africa discussed including access to raw materials, costs of validation studies, finding staff with the skillset to maintain a QMS and IVD quality assurance training
  - Strong interest from manufacturers in understanding the WHO technical specifications for prequalification

WHO EUL: Monkeypox virus NAT IVDs

The detection and rapid spread of a new clade (Clade Ib) of Monkeypox virus in eastern DRC, its detection in neighboring countries that had not previously reported mpox, and the potential for further spread within Africa and beyond has prompted the renewal of its classification as a PHEIC as of 14. August 2024

On 28 August WHO invited manufacturers to submit IVDs for Monkeypox
virus nucleic acid detection for review by WHO through the EUL mechanism

The EUL scope includes IVDs for the detection of mpox nucleic acid (multiplex assays, detecting more than one nonvariola Orthopox virus targets, at least one target must be Monkeypox virus specific)
Differentiation of Monkeypox virus clades I and II is preferred but not required.

24-08-28-invitation-to-manufacturers-of-mpxv-nat.pdf (who.int)

Coming next

- New changes assessment guidance:
  - Draft developed with enhanced reliance implementation
  - Introduction of a revised procedure for change reviews
    - High-impact changes review
    - Low/moderate impact changes review
    - Abridged assessment for changes approved by recognized NRAs
  - Amended change request form detailing minimal expected documentation depending on the type of change
  - Consultation planned in Q4 2024 and implementation in 2025
- Consultation on process changes:
  - Planned in Q4 2024 with rollout of new processes in 2025
- New abridged assessment guidance:
  - Planned in 2025
  - Enhanced reliance on recognized approvals

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