

RHI Update- AFRICAN MEDICAL DEVICES FORUM(AMDF)

March-Sept 2025

Paulyne Wairimu
AMDF-Chair, PPB-Kenya
17th September 2025
Hokkaido, Japan





Background

- Election of the African Medicines Agency (AMA) Director General
- 16th AMRH Steering Committee Meeting 17-18 July 2025
- 4th MDA-TC and 3rd Session of the Continental Joint Review of Mpox in-vitro Diagnostics August 11-14th 2025
- Guidelines for Implementation by AMDF
- Sensitization Webinar-Capacity Building for AMDF
- Published call for EOIs for Assessors, Auditors and Members to the QMS –TWG under MDA-TC



African Medicines Agency (AMA) -DG

- The Conference of State Parties (CoSP) of the African Medicines Agency (AMA)
- Appointed Dr. Delese Mimi Darko (Republic of Ghana and Former CEO-Ghana FDA) on 4th June 2025
- The appointment of the DG is crucial towards steering the regulatory oversight of Medical Products (including Medical Devices and IVDs) across Africa
- A single umbrella body- The African Medicines Agency
- Tenure of office to start 1st September 2025





16th AMRH Steering Committee Meeting 17-18 July 2025

- Emergency Use Listing (EUL) for Mpox In Vitro Diagnostics Facilitated by MDA-TC
- Continental Listing of Cobas® MPXV- real-time PCR assay for the qualitative detection of DNA from Monkeypox virus - AMDF/EUL/00
- Continental Listing of RADIONE Mpox Detection Kit – AMDF/EUL/006
- <https://www.nepad.org/news/public-notice-amrh-steering-committee-approves-emergency-use-listing-of-two-mpox>



4th MDA-TC and 3rd Dossier Review Plenary

- Assessment of new IVDs for continental Emergency Use Listing
- Review of Quality management System audit team for the continental listing procedure (TORs development)
- Criteria for Manufacturers on the QMS



IMDRF International Medical Device
Regulators Forum



AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

African Medical Devices Forum:
PROCEDURE FOR FIELD SAFETY
CORRECTIVE ACTIONS FOR
MEDICAL DEVICES

2024



AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

GUIDELINES ON REQUIREMENTS ON
LABELLING OF MEDICAL DEVICES
INCLUDING IN VITRO DIAGNOSTIC
MEDICAL DEVICES

2024



Implementation of the four guidelines

- Procedure for FSCA for Medical Devices
- Guidelines on requirements on labelling of medical devices including IVDs
- Alignment with IMDRF guidance documents on the same



Implementation of the four guidelines

- Guideline for authorization of IVD medical devices during public health emergencies
- Guidelines for registration of manufacturers, and other parties and listing of medical devices and IVDs
- Alignment with IMDRF guidance documents





Regulatory Convergence through Capacity Building

- Capacity building of NRA's through adoption/adaption of the developed guidelines
- Attended by Regulators across Africa (120 attendees)
- Presentations in multilingual (English and French)
- Translation in English, French and Portuguese to facilitate widespread coverage in the continent
- A platform for exchange of expertise and knowledge
- Webinar series for different materials



AFRICAN MEDICAL DEVICES FORUM (AMDF)
REGULATORY GUIDELINES FOR MEDICAL
DEVICES INCLUDING IN VITRO DIAGNOSTICS

GUIDELINES DISSEMINATION WEBINAR

Participants:

National Regulatory Authorities from
AU Member States

The webinar will be in English with
simultaneous interpretation into
French and Portuguese

20 AUGUST 2025
13:00PM - 15:00PM CET

REGISTER HERE

About the Webinar:

The World Health Organization (WHO) in collaboration with the African Union Development Agency (AUDA NEPAD) and African Medical Devices Forum (AMDF) is organizing a Webinar to disseminate four Guidelines; Labelling, Emergency Use Authorization (EUA), Field Safety Corrective Actions (FSCA), and Registration of Manufacturers and Other Parties and Listing of Medical Devices and IVDs—approved by the AMRH Steering Committee.

These guidelines form part of AMDF's broader initiative to advance a harmonized regulatory framework and strengthen oversight of medical devices across Africa.

The webinar will present these guidelines to National Regulatory Authorities (NRAs), providing them with best practices to promote regulatory alignment, reliance, assurance of quality, safety, and performance within Africa's evolving medical devices regulatory landscape.




Published call for EOIs for Assessors, Auditors and Members to the QMS –TWG under MDA-TC

-a call has been published to invite experts from across the continent to join the MDA-TC under its pool of experts and memberships to the QMS-TWG

-Targeting Medical Devices Regulatory Experts in Africa

-The call is on the first ever electronic continental regulatory experts solution (e-CRES)

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eCRES
(ELECTRONIC CONTINENTAL REGULATORY EXPERTS SOLUTION)

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Active Expressions of Interest Requests - Regulatory Functions

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<input type="checkbox"/>	Actions	Eoi Reference No	Closing Date	Expression of Interest Category	Engagement Type	Expression of Interest Title	Background Information
	Preview and Apply	ECRES-002025/EOI? POST/0009		Assessment/Evaluation	Hybrid	REQUEST FOR EXPRESSION	Since its inception in 2009, the ...
	Preview and Apply	ECRES-002025/EOI? POST/0010		Medical Devices Assessments Technical Committee	Hybrid	REQUEST FOR EXPRESSION	The African Medicines Regulat ...

AUDA NEPAD - eCRES

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Medical Devices Software Guideline- PPB Kenya

- New Guideline on regulation of Medical Device Software registration in Kenya
- Outlining the current best practices and Good regulatory practices
- Considerations for Cybersecurity in Medical Devices
- Incorporating use of AI and Machine Learning Technologies in Medical Devices
- Support from the IMDRF Working Group Members US-FDA and Health Canada



REPUBLIC OF KENYA

**MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD**

**GUIDELINE ON REGULATION OF MEDICAL DEVICE SOFTWARE
IN KENYA**

DRAFT

JUNE, 2025



Thank you/Questions