IMDRF International Medical Device Regulators Forum

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

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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

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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

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AUDA-NEPAD AFRICAN UNION DEVELOPMENT AGENCY

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

2024

World Health Organization

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

AUDA-NEPAD AFRICAN UNION DEVELOPMENT AGENCY

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

2024

AMRH African Medicines Regulatory Harmonisation Programme

IMDRF International Medical Device Regulators Forum

AUDA-NEPAD AFRICAN UNION DEVELOPMENT AGENCY

AFRICAN MEDICAL DEVICES FORUM

Guidelines for Authorization of in vitro diagnostic medical devices during public health emergencies

2025

AMRH African Medicines Regulatory Harmonisation Programme

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

AUDA-NEPAD AFRICAN UNION DEVELOPMENT AGENCY

GUIDELINES FOR REGISTRATION OF MANUFACTURERS, AND OTHER PARTIES AND LISTING OF MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES

2024

AMRH African Medicines Regulatory Harmonisation Programme

IMDRF International Medical Device Regulators Forum

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

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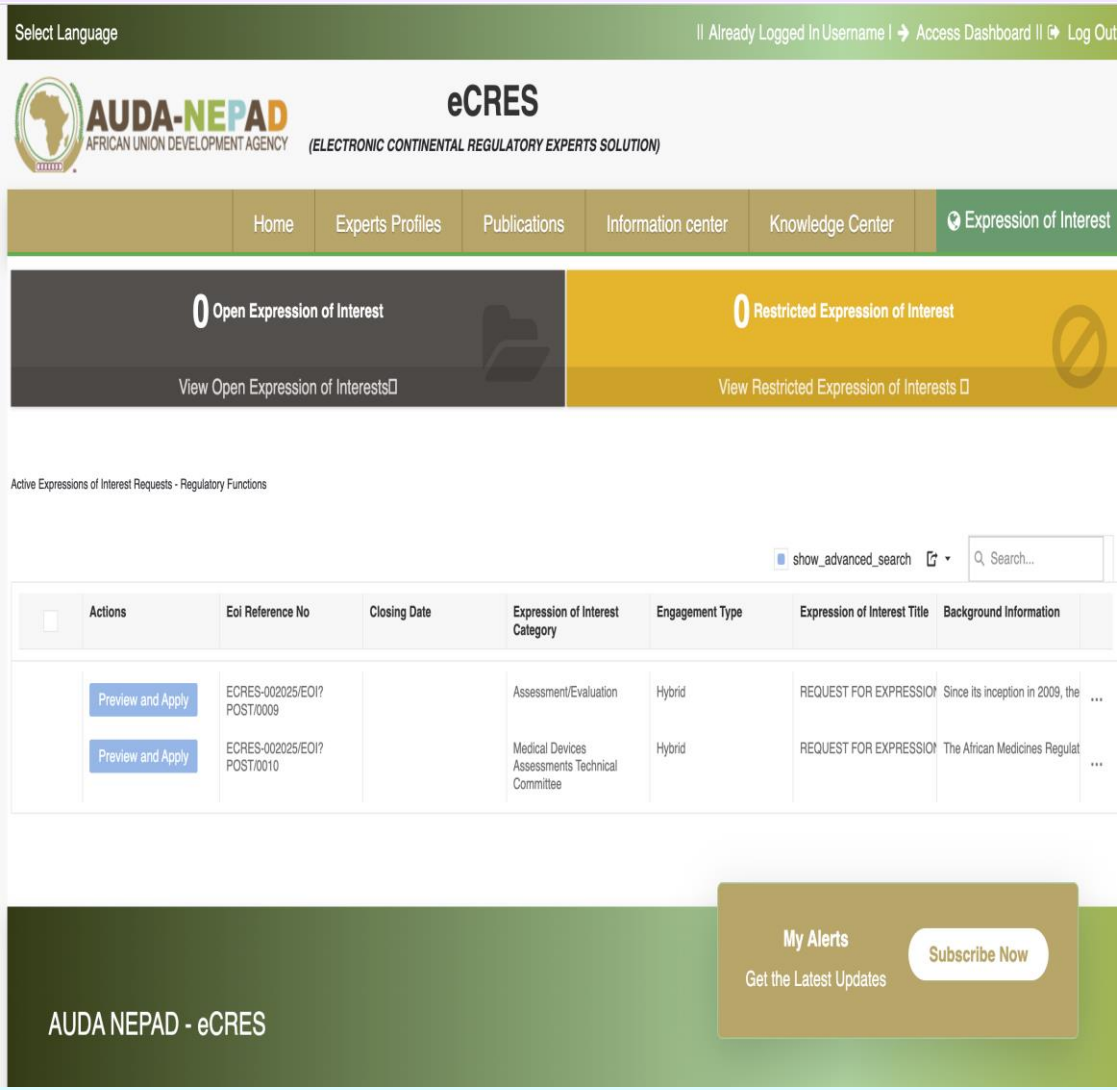
Published call for EOIs for Assessors, Auditors and Members to the QMS –TWG under MDA-TC

-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

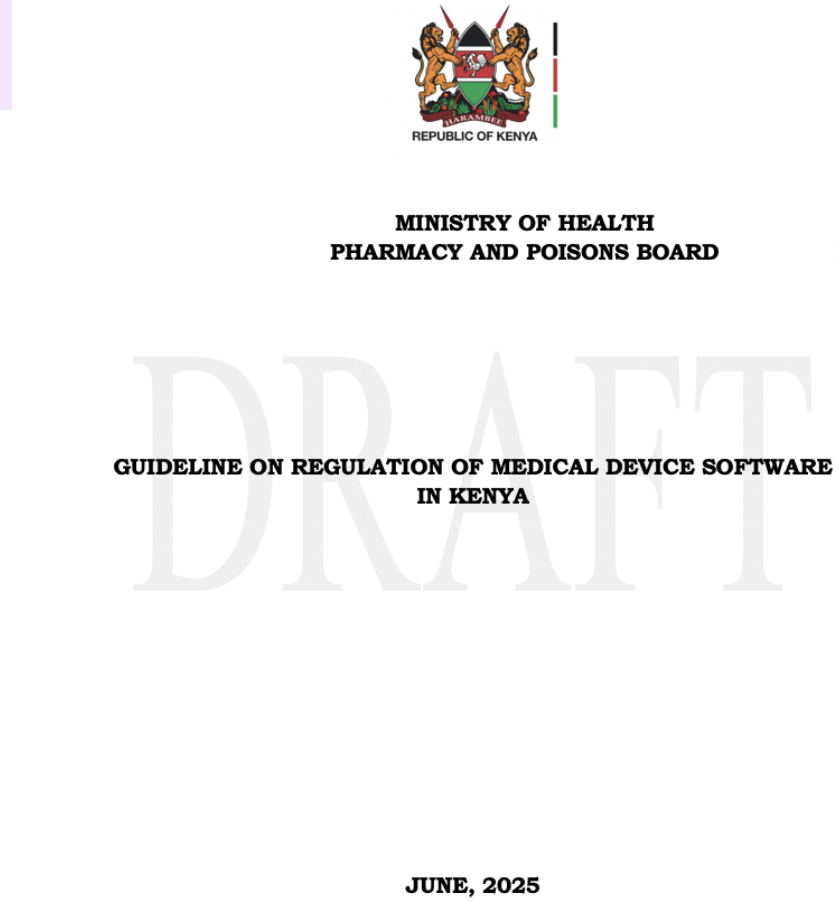
-Targeting Medical Devices Regulatory Experts in Africa

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



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

DRAFT

GUIDELINE ON REGULATION OF MEDICAL DEVICE SOFTWARE IN KENYA

JUNE, 2025

Thank you/Questions