

AMDF's Role in Shaping a Unified Regulatory Future for Medical Devices

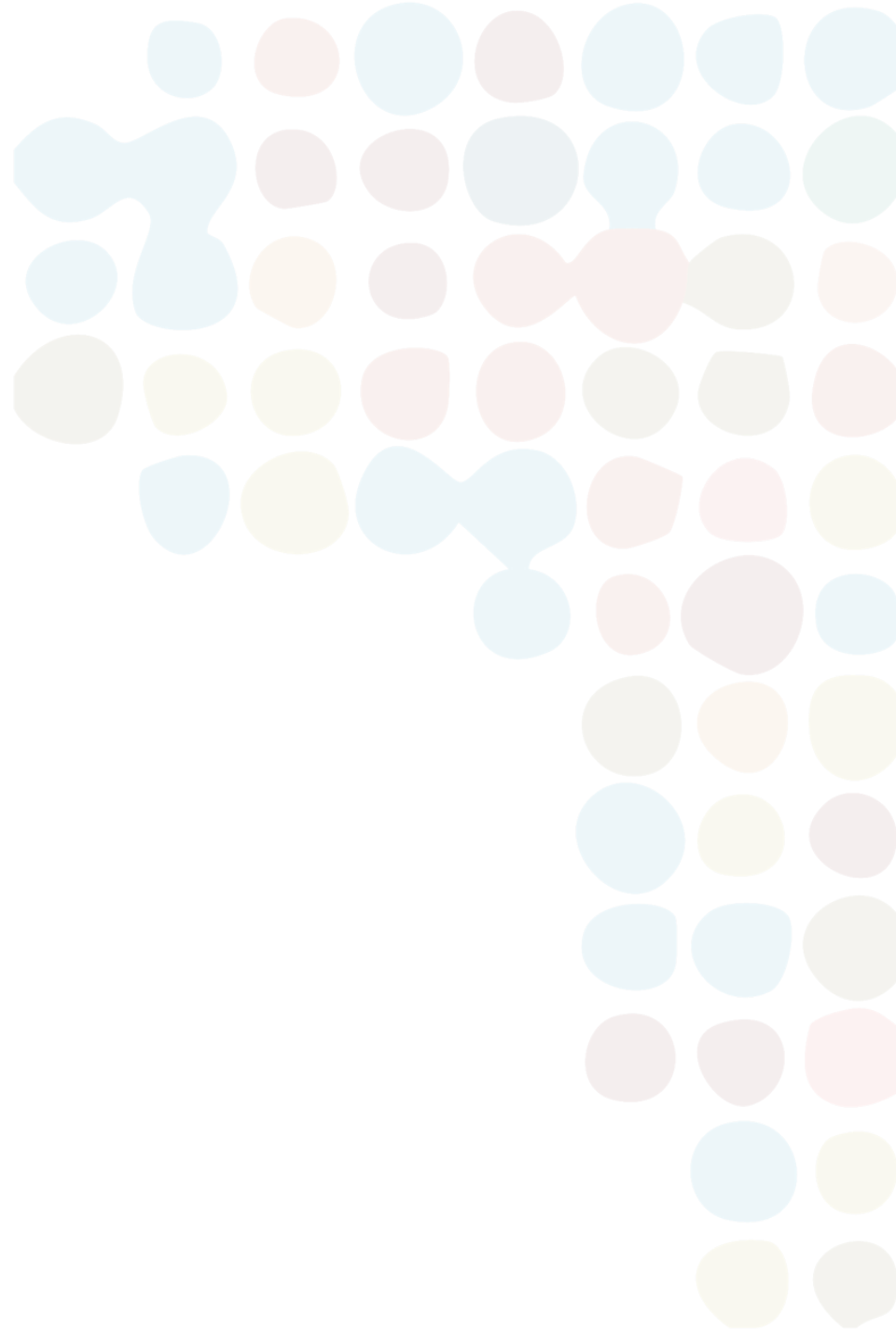
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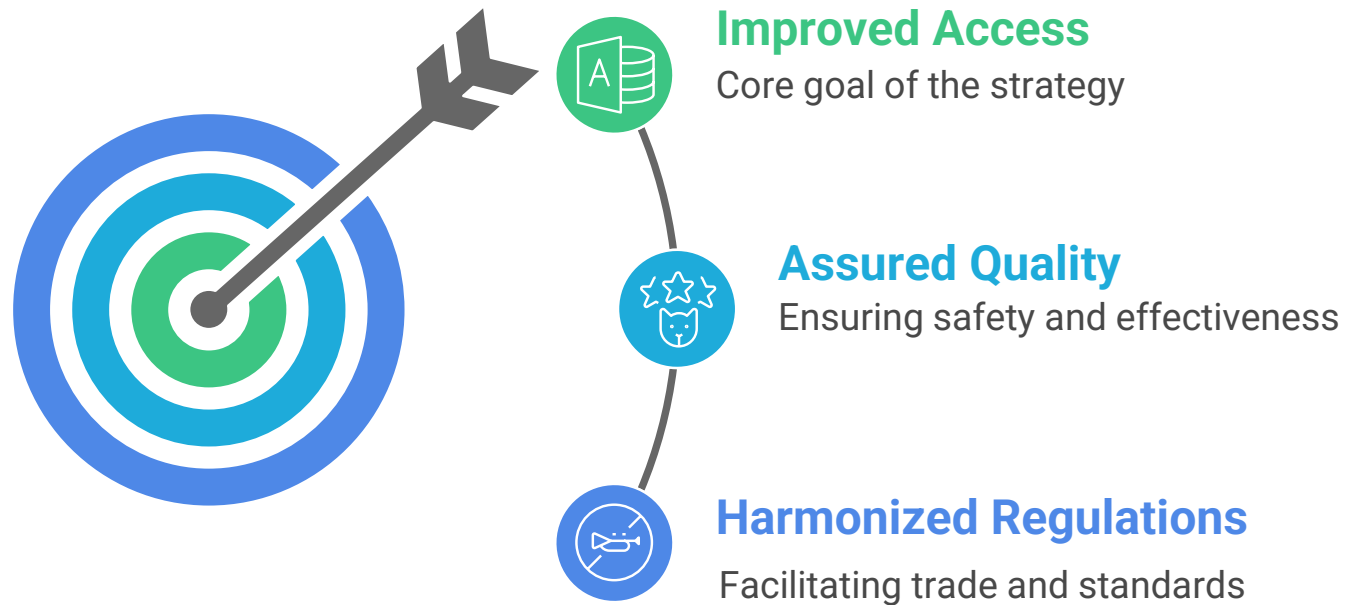
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African Medical Devices Forum (AMDF) Overview

- A technical committee under the African Medicines Regulatory Harmonization (AMRH) Programme, jointly hosted by AUDA-NEPAD (African union development agency) and WHO.



Egypt's Leadership in AMDF

- In April 2025, Kenya (Pharmacy and Poison Board) was elected as chair of AMDF, and Egypt (Egyptian Drug Authority) was elected Vice-Chair of the AMDF for a three-year term (2025-2028).
- Reflects continental confidence in Egypt's regulatory leadership.
- Reinforces commitment to advancing medical device regulation across Africa.



IMDRF-Aligned Regulatory Guidelines



Labelling Requirements

Guidelines for labelling medical devices, including Invitro diagnostics.



Emergency Authorization

Procedures for authorizing in vitro diagnostic medical devices during public health emergencies.



Registration and Listing

Registration of manufacturers and listing of medical devices.



Field Safety Actions

Procedure for field safety corrective actions for medical devices.

Egyptian Drug Authority at the 4th MDA-TC Meeting

- Reviewed **3** applications for **Mpox molecular diagnostic tests** (RT-PCR).
- **Approved** additional data requirements and technical references for the QMS Audit Working Group.
- **Adopted** joint technical recommendations, reference documents, and assessment tools.
- Advanced Agenda 2063 through coordinated regional and continental initiatives.

Regulatory Convergence through Capacity Building

- Capacity building on **strengthening oversight of medical devices and IVDs for 120+ regulators** across Africa .



**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.

Expressions of Interest (EOI) for Selection of Technical File Assessors and ISO13485 Based QMS Auditors

In September 2025, The African Medicines Regulatory Harmonization (AMRH) Initiative, under AUDA-NEPAD, invited qualified experts from African Union Member States to express interest in serving as continental assessors and auditors. These experts will support the Medical Device Assessment Technical Committee (MDA-TC) in strengthening regulatory oversight for medical devices and in-vitro diagnostics (IVDs) across Africa.



For A Healthier Africa
AFRiSUMMIT

2nd - 5th November 2025

Hilton Grand Nile Hotel, Cairo - Egypt



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THANK YOU