International Medical Device Regulators Forum
22nd Management Committee Meeting
Stakeholder Open Forum

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AMDF Chair/PPB-K
Sydney, Australia
13th September 2022
Outline

• Governance under AMRH
• AMDF Leadership
• 5 Year Strategic Plan
• AMDF Work Plan 2022
• Key Achievements
• Areas of support
Vision and Mission

- AMDF is the Continental Technical Working Group for Medical Devices including In vitro diagnostics.

- AMDF works with medical devices regulators in Africa

**Vision**: enable access to medical devices and in vitro diagnostics of assured quality, safety, and performance across Africa.

**Mission**: is to study and recommend ways to harmonize medical devices and diagnostics regulation in Africa
AMRH Governance Framework

African Medicines Regulators Conference (AMRC) ASSEMBLY

AMRH Steering Committee

Technical Working Groups (TWGs)

AMDF TWG MD&IVDS

WHO/UNPAD Secretariat

NRAs

AMRH SC

RECs / TWG on medical devices including IVDs

AMDH Partnership Platform

AFMRH Governance Framework
AMDF Leadership (2022-2025)

During the The Seventh African Medicines Regulators’ Conference (AMRC VII) held in November 2021, AMDF leadership was elected as below.

- Chairperson: Paulyne Wairimu (PPB- Kenya)
- Vice Chair: Dimakatso Mathibe (SAHPRA-South Africa)
- Rapporteur: Frank Laban (ZAMRA- Zambia)

Joint Secretariat - AUDA-NEPAD and World Health Organization
AMDF 5 Years Strategic Plan

• **Strategic Priorities**
  
  • **Strategic Priority 1**: Support the establishment and operational implementation of the Africa Medicines Agency.

  • **Strategic Priority 2**: Advance and promote continental harmonization, mutual recognition, and reliance of medical device regulations in all Regional Economic Communities.

  • **Strategic Priority 3**: Encourage innovation on the continent through local production of quality-assured essential medical devices and in vitro diagnostics as sustainable path in ensuring self-reliance.

  • **Strategic Priority 4**: Engage in strategic technical and financial partnerships to build strong coalition of partners and country advocates towards sustainable adoption and implementation of AMDF objectives.

  • **Strategic Priority 5**: Build technical capacity of national regulatory agencies in medical device including
    
    • IVD regulatory frameworks, guidelines, and quality management systems.

  • **Strategic Priority 6**: Coordinate and facilitate implementation of joint regulatory activities (inspection,
    
    • dossier reviews and post marketing surveillance of medical devices including IVDs).
AMDF Workplan 2022

1. Advance and promote African continent harmonization, mutual recognition, and reliance of medical devices regulations in Africa.

2. Encourage innovation in medical devices including in-vitro diagnostics on the continent through local production of quality-assured essential medical devices and in-vitro diagnostics as sustainable path in ensuring self-reliance.

3. Advance the sensitization, adoption and roll out of AMDF strategic priorities across member states, partners, and stakeholders.

4. Continue to build technical capacity of national regulatory agencies in medical devices and IVDs regulatory frameworks, guidelines, and quality management systems.
AMDF Key Achievements

- Virtual Meeting with Technical Committee Members and partners
  - Present on the AMDF Workplan 2022 and endorsed guidelines for domestication by NRAs

- Development and endorsement of 4 Guidelines for use by NRA’s
  - 17th - 18th May 2022 NRA Workshop to sensitize and disseminate the guidance documents for adoption and adaption

- 6 New guidelines under review
  - in accordance to new areas of interest to develop technical material

- Finalization of the Strategic Plan by AU-D-NEPAD

- Global Model Regulatory Framework revision input my AMDF Technical Experts

- Kenya is the first country to be Piloted for the Global Benchmarking Tool Plus Medical Devices (GBT+MD Tool)
Partner/Stakeholder Support to AMDF

• Partners to support key interventions for the strategic priorities
• African Medicines Agency – AMDF is a key Asset in guiding the development of Technical Expertise and Documents for use by the AMA.
• Harmonization of internationally recognized standards for use in Africa, in supporting Manufacturing of MDs and IVDs
• Strengthening research and development of MDs in the African continent
• Programs or initiatives to support Technical Capacity building for Regulatory Authorities (through adoption of international frameworks, virtual platforms for training and workshops, webinars)
• Global Bench Marking for Medical Devices (GBT+MD) tool
Thank you!