AFRICA MEDICAL DEVICES FORUM

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Outline

- AMDF Governance under AMRH
- achievements
- AMDF Workplan 2022 (objectives)
- AMDF Workplan(Activities)
- Summary
- Acknowledgments

Vision and Mission

➢Vision

Enable access to medical devices and diagnostics of assured quality, safety, and performance across Africa.

➢ Mission

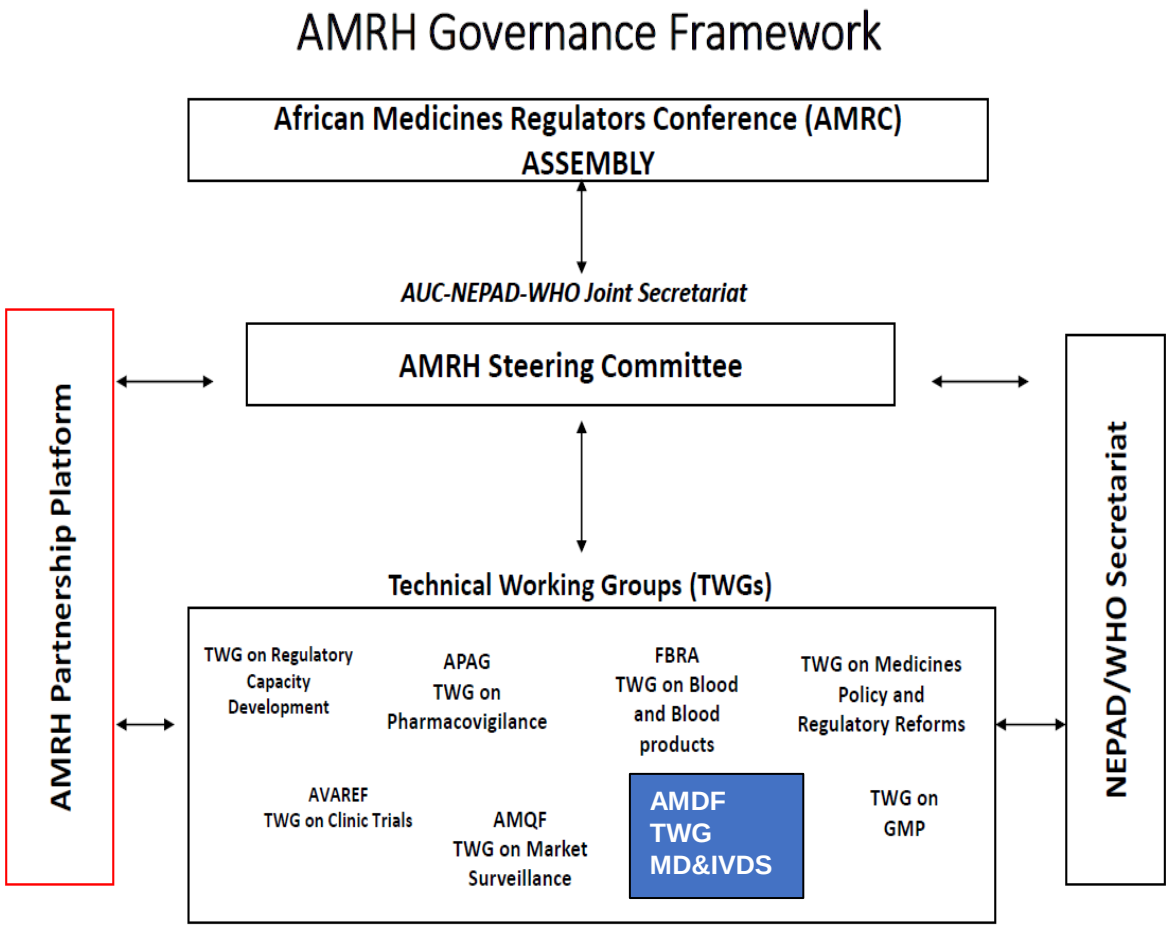
Study and recommend ways to harmonize medical devices and diagnostics regulation in Africa

➢Scope:

Capacity building on registration and common dossier submissions; quality audit and inspection; clinical performance studies; and post-market surveillance.

Conducting training programs and providing resources to NRAs as part of capacity building.

AMRH Governance Framework



AMDF MAIN ACHIEVEMENT

- Established the AMDF Technical Committee and three sub-Working Groups (Premarket, Placing on the market and PMS) based on the approved ToRs.
- Established AMDF COVID-19 Task Force: Preparing and sharing
  - list of COVID-19 NAT and Antigen assays
  - list of priority COVID-19 priority medical devices and PPE
  - list of local manufacturer in Africa
  - Donation guideline, SOP and forms for reporting SF MDs incl. IVDs
- Development of four AMDF guidelines in English, translation of the guidelines in French is on going.
- Implemented AMDF activities through the 2019, 2020 and 2021 workplans. Draft workplan has been developed for 2022.
- Development of a 5 years AMDF strategic plan (2022 -2026).
- Held elections of the new leadership of AMDF on 24 November 2021.

AMDF WORKPLAN FOR 2022 OBJECTIVES

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 WORKPLAN FOR 2022 OBJECTIVES AND ACTIVITIES

- **Objective 1**: Advance and promote African continent harmonization, mutual recognition, and reliance of medical devices regulations in Africa
  - Promote adoption of the WHO Global Model regulatory framework for medical devices including IVDs
  - Present AMDF activities in various technical and non technical forums to promote AMDF work

- **Objective 2** :Encourage innovation in MD &IVDs on the continent through local production of quality-assured essential medical devices and in-vitro diagnostics as sustainable path in ensuring self-reliance
  - Disseminate and sensitize adoption of the AMDF guidance on Auditing of Manufacturing sites based on ISO 13485 by regulators
  - Work with interested partners and manufacturers to support local production of Medical Devices including IVDs

- **Objective 3**: Advance the sensitization, adoption and roll out of AMDF strategic priorities across member states, partners, and stakeholders
  - Finalize the development of the AMDF 5-year strategic plan 2022- 2027
  - Disseminate the AMDF strategic plan in various platforms (website, social media, webinars, workshops etc.)

- **Objective 4**: Continue to build technical capacity of national regulatory agencies in medical devices and IVDs regulatory frameworks, guidelines, and quality management systems
  - Promote and support twinning practices among NRAs
  - Training of Experts on assessment of Technical files
  - Guidance document on assessment and MA issuance during Emergencies

Summary

- Regulatory Harmonization efforts in Africa
- Promoting Reliance
- Equipping Regulators in Africa with tools for strengthening regulation
- Work in partnership or collaboration
- Africa Medicines Agency Ratification- AMDF as an Technical Committee under AMRH Initiative for Advisory

Acknowledgment

- AMDF wish to Acknowledge support from
  - World Health Organization
  - AUDA-NEPAD
  - Saudi FDA
  - South African NHLS
  - ASLM
  - MTaPS
  - USP
  - African regulators who have been actively participated in AMDF activities

Thank you!