African Union Development Agency (AUDA-NEPAD)

NEPAD TRANSFORMING AFRICA

World Health Organization

African Medical Devices Forum

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

**Paulyne Wairimu**

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

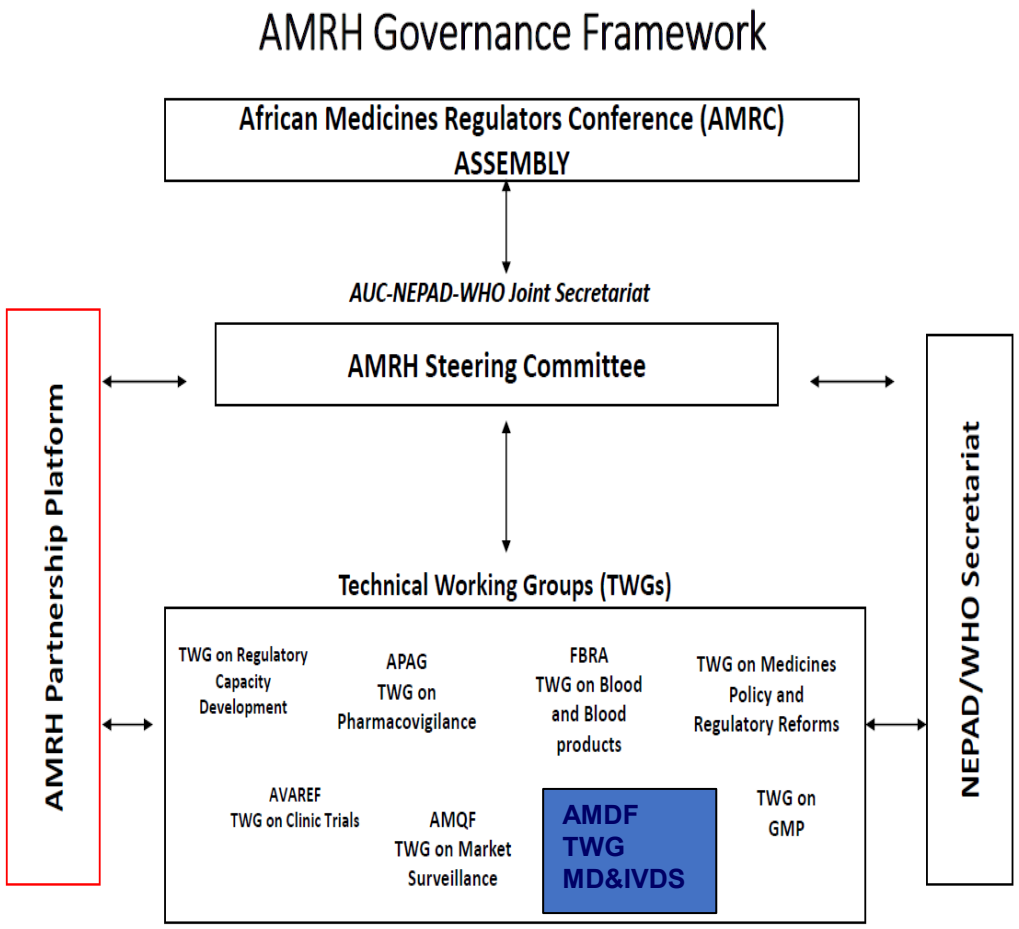
-AMDF is the Continental Technical Working Group for Medical Devices including In vitro diagnostics.

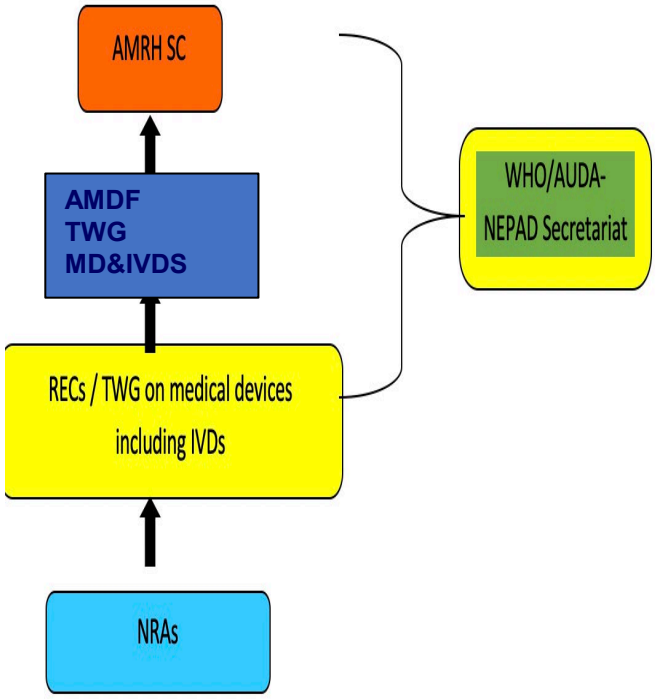
-AMDF  works with medical devices regulators in Africa

***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



# 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 AUDA-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!