AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AMDF Workplan Jan –Dec 2022

The Seventh African Medicines Regulators' Conference (AMRC VII)

Dimakatso Mathibe AMDF (WG Member)/SAHPRA- South Africa

24TH NOVEMBER 2021

AMDF 2022 Objective

1.

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

2

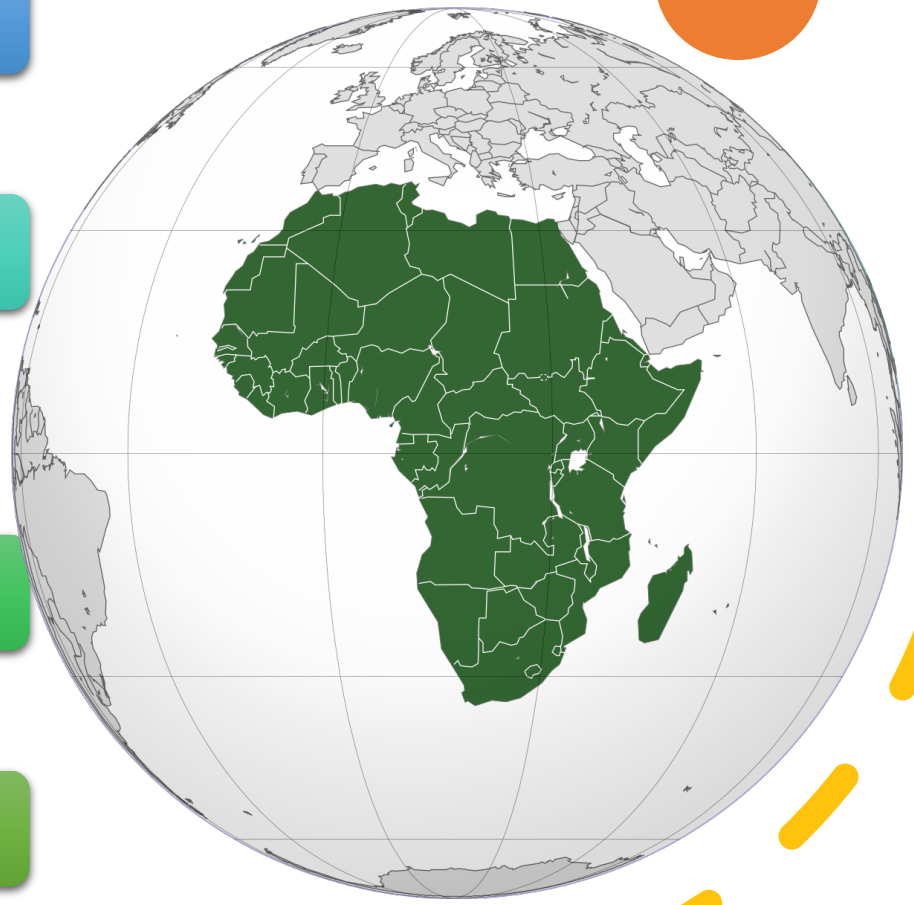
- Encourage innovation in medical devices including in-vitro diagnostics on the continent through local production of quality-assured essential medical devices and in-vitro diagnostics as sustainable path in ensuring self-reliance

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



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

Activities:

- ❖ 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
- ❖ Conduct quarterly sensitization and consultative Webinars with African regulators, RECs and other stakeholders
- ❖ Develop articles and Newsletters on AMDF activities (quarterly)

Activities:

- 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

Activities:

- ❖ 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

- Conduct self assessment and develop institutional development plans to strengthen regulatory systems for medical devices including IVDs.
- Promote and support twinning practices among NRAs
- To train experts on assessment of technical file (s) for selected medical devices including in vitro diagnostics.
- Develop guidance documents on assessment and issuance of Market Authorization of medical devices including IVDs during emergencies

Thank you!