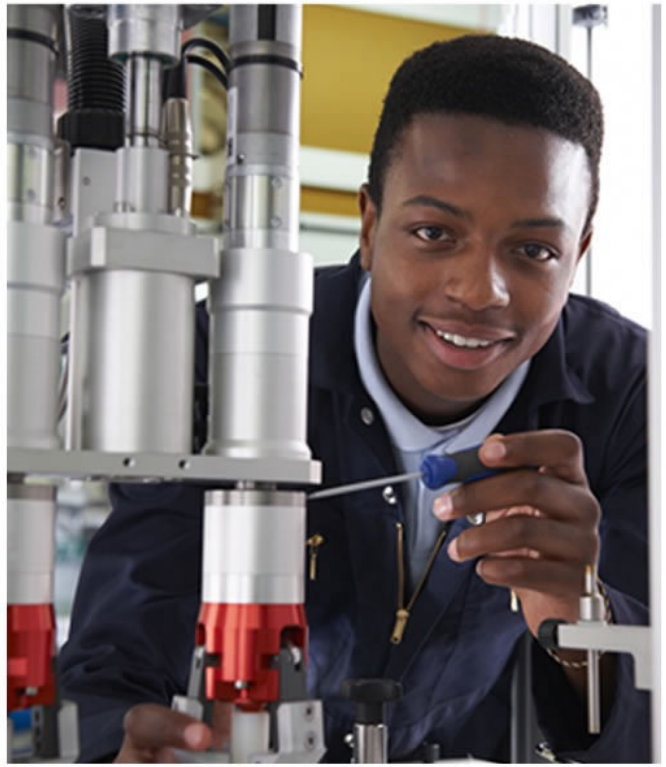
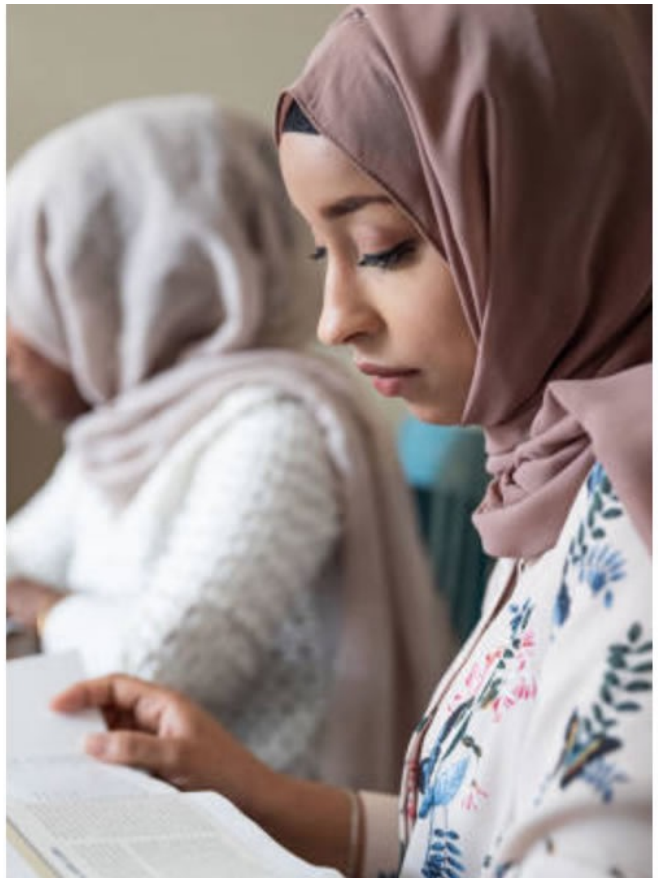
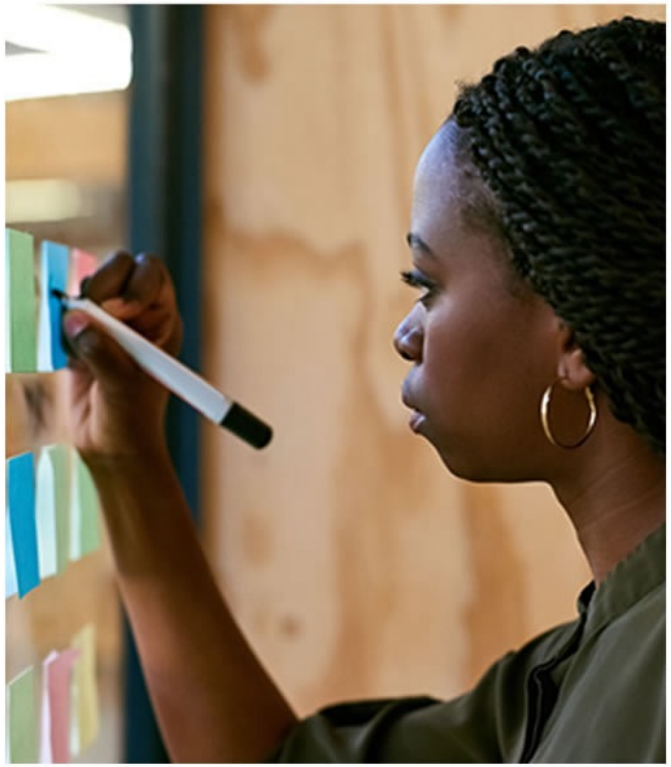
AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AMDF FEEDBACK SESSION







The Seventh African Medicines Regulators' Conference (AMRC VII)

PAULYNE WAIRIMU I Chair AMDF/PPB-K.

25TH NOVEMBER 2021

Outline

- AMDF achievements
- AMDF Workplan 2022 (objectives)
- AMDF Workplan(Activities)
- Recommendations

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

RECOMMENDATIONS

- Request Member states to adapt and adopt approved four AMDF guidelines;
- Continue to seek the support of the AMRH Steering committee to strengthen Regulatory Capacity for regulation of medical devices including medical devices.
- Request REC secretariat to support implementation of the proposed interventions as outlined in the AMDF 5 years AMDF Strategic plan;
- Seek support from regulators and RECs Representatives to participate in AMDF activities through the AMDF subWG;
- Requests the AMRC to approve the draft AMDF Workplan for 2022.
- Seek partners support in the implementation of the AMDF 5 years strategic plan once approved by the AMRH SC.

Acknowledgement

- 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!