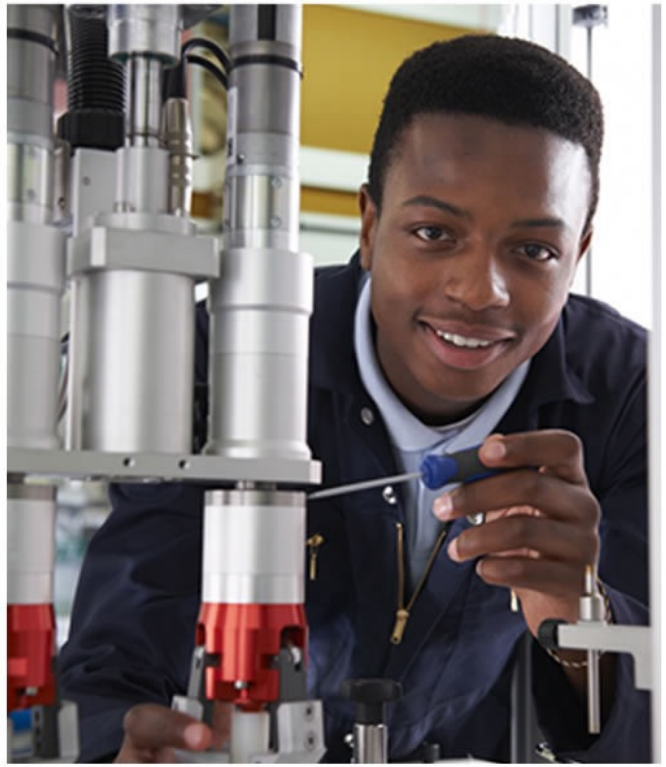
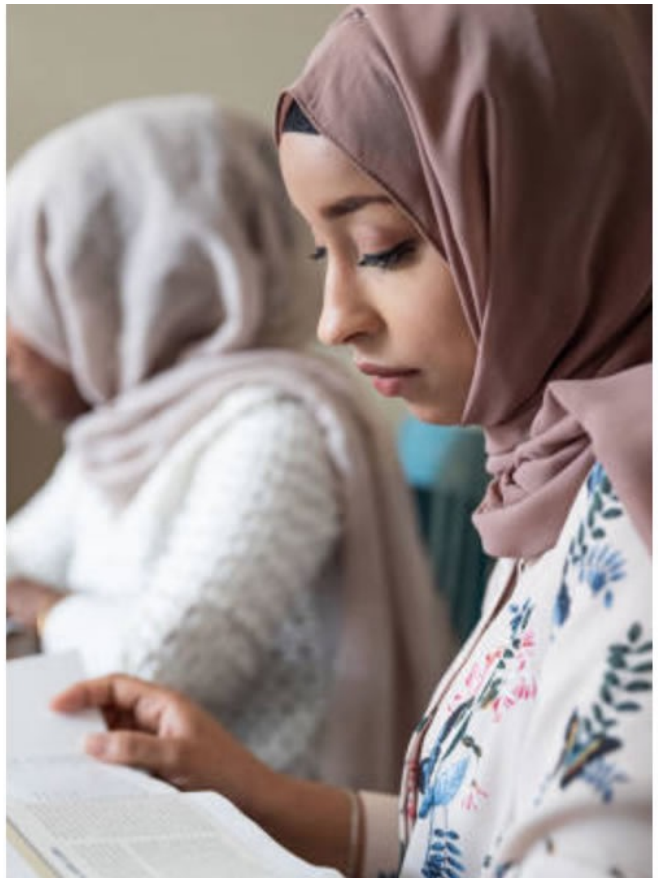
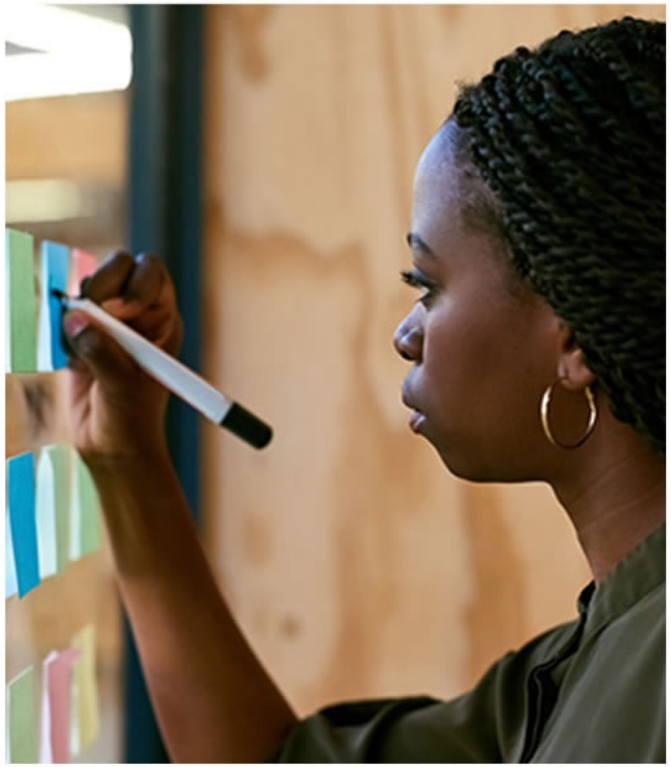
AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AMDF PROGRESS REPORT 2021







The Seventh African Medicines Regulators' Conference (AMRC VII)

PAULYNE WAIRIMU Interim Chair AMDF/PPB-K.

24TH NOVEMBER 2021

OUTLINE

-AMDF Planned activities for 2021

-AMDF Achievement

-Recommendations

AMDF 2021 Planned Objective

1. To promote the work of AMDF as a Technical Committee of the African Medicines Regulatory Harmonization Initiative.
2. Support implementation of harmonized regulatory framework for medical devices including in vitro diagnostic medical devices
3. To establish and strengthen platforms for sharing developments in regulation, research and innovations on medical devices including in-vitro diagnostics.
4. To improve human resource capacity for the regulation of medical devices including in vitro diagnostics.

Objective 1: To promote the work of AMDF as a Technical Committee of the African Medicines Regulatory Harmonization Initiative.

Activities:

- AMDF leadership represented AMDF in the following meetings:
  - Extra Ordinary International Conference for Drug regulatory authorities (ICDRA),
  - South African Medical Technology Industry Association (SAMED)
  - UNFPA/Afro CondomNet workshop to sensitize regulation of MDS and improving testing of MDs and IVDs.
  - Expect to participate in the Global Harmonization Working Party (GHWP) in December 2021

Objective 2: Support implementation of harmonized regulatory framework for medical devices including in vitro diagnostic medical devices

Activities:

guidelines developed and approved by the AMDF TC;

- Guidelines on regulatory requirements for issuance of market authorization of medical devices including in-vitro diagnostic medical devices
- Guidelines for registration of medical devices establishments
- Guidelines on import and export of medical devices including in-vitro diagnostic medical devices
- Guidelines for inspection of manufacturing site(s) for assessment of the quality management system of medical devices based on ISO 13485:2016

- *The four guidelines were endorsed for approval at the 9th Meeting of the Steering Committee on Regulatory Systems Strengthening and Harmonization Initiatives in Africa*

- Translation of these guidelines into French and formatting is in advance stage
- A guidelines on assessment and approval of medical devices including IVDs during Emergencies is currently being discussed by Sub-WG

Objective 2: Support implementation of harmonized regulatory framework for medical devices including in vitro diagnostic medical devices

Activities:

- Compiled and shared with regulators COVID-19 IVDs, priority medical devices and PPEs which were assessed by WHO and other mature NRA for use during Emergency.
- Seven (7) lists have been compiled so far since April 2020 and expect the 8th list to be submitted to the AMRH SC.
- The lists can be found at AMDF website http://amdfnra.org/#

Objective 2: Support implementation of harmonized regulatory framework for medical devices including in vitro diagnostic medical devices

- Two (2) days workshop in advocating collaboration in regulatory controls for Medical Devices and IVDs (AMDF ASLM) conducted in February 2021 and attended by apx. 90 experts.
  - Sensitize Governments and their respective regulatory authorities to adopt the recommendations outlined in the WHO Global Model Regulatory Framework for medical devices including invitro diagnostics.
  - Establish collaboration between Regulators and Laboratory experts in all processes in regulation of medical devices including in vitro diagnostics in order to fully utilize available expertise, increased efficiency and capacity building
  - WHO to continue to support countries and RECs in the development of regulatory requirements and guidance documents to address all key elements recommended for basic level and later on to expanded levels of controls and enforcement

Objective 3:To improve human resource capacity for the regulation of medical devices including in vitro diagnostics.

Activities:

- 114 Regulators participated in the AMDF Basic Level online training course (self learning) for regulators on regulation of IVDs MDs developed with support of WHO.
    - 114 regulators have taken the course and have found it to be very useful

- Organized four (4) days workshop in March 2021 on technical files assessment and post market approaches for COVID19 assays in collaboration with SFDA.

    - The workshop was attended by more than 100 Regulators
    - Countries were encouraged to implement reliance
    - Post market surveillance and market surveillance are critical in ensuring continued quality safety and performance of medical devices including IVDs

Objective 3:To improve human resource capacity for the regulation of medical devices including in vitro diagnostics.

Activities:

- In November 2021 organized four (4) days Workshop on Post market surveillance and market surveillance for regulators of Medical Devices in collaboration with SFDA.
  - Appx 120 participants attended
  - 4 Country experiences were shared (Kenya, South Africa, Mali, Uganda and Senegal)

Objective 4:To establish and strengthen platforms for sharing developments in regulation, research and innovations on medical devices including in-vitro diagnostics

Activities:

- Regulators continued using the WHO/AMDF Med-Net platform
- AMDF Webpage was established/ (under AUDA-NEPAD website).
  - Currently being hosted by South Africa National Health Laboratory Network due to technical challenges http://amdfnra.org/
    - Regulatory updates
    - AMDF Guidelines
    - AMDF Newsletter (AMRH Q1&Q2 2021Newsletter)
    - Resource page

Key Messages

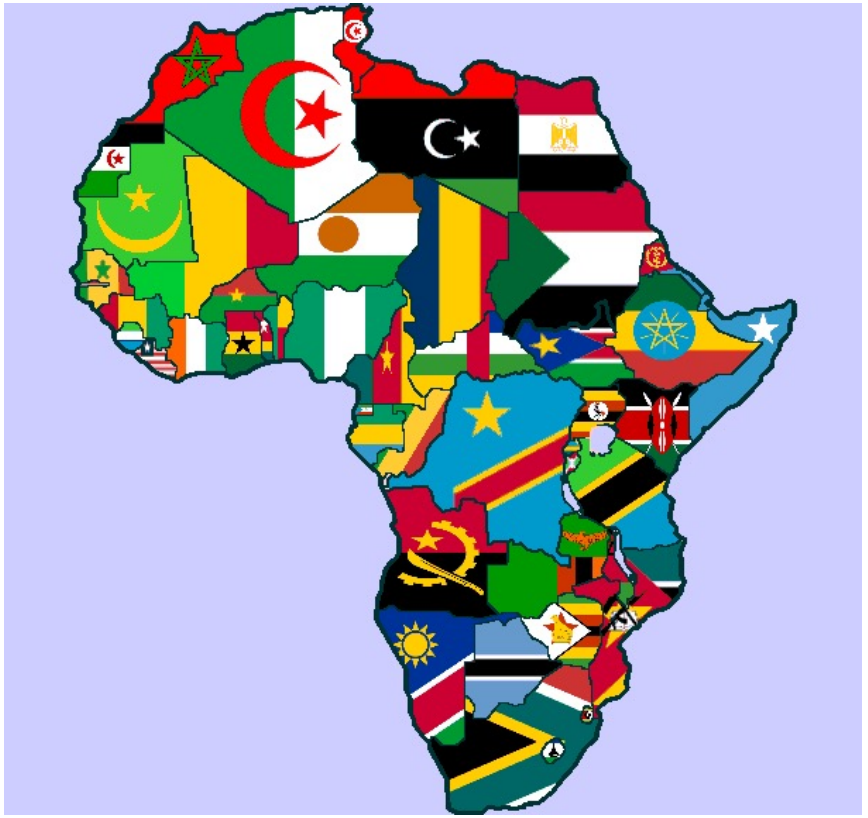
- Regulators are encouraged to actively engage and participate in regional activities
- Encourage experts to participate in AMDF activities through the subWG
- Adoption/Adaption of the AMDF guidance documents developed through the AMRH (AMDF- TC)
- Continue to use existing AMDRF Platforms for network and information sharing
- Encourage African regulators to participate and contributes in international discussions related to Medical Devices regulation such WHO GBT+, GMRF, IMDRF etc
- Seek Partner support in key areas of regulation of medical devices

Recommendations

- To support the work of AMDF in strengthening and harmonization of Medical Devices and IVDs,
- Partners to support in the implementation of the 5 years strategic plan
  - Further Partner Support of Medical Devices regulation in capacity building of experts in Africa
  - Encourage regulators to participate in AMDF activities
  - Inclusion in AMDF activities of RECs workplan through the Sub-working Groups
  - Adoption of the four guideline that have been developed by AMDF

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!