Fifth Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA V) & The Seventh African Medicines Regulators' Conference (AMRC VII)

AMDF Technical Committee Meeting Report

24 November 2021

1. **Opening remarks**:

The acting Chair of AMDF Ms Paulyne Wairimu opened the meeting by welcoming AMDF members to the meeting, the time when AMDF has reached an age of three years. She also informed the participants that they will get an opportunity to hear the progress made and AMDF future plans.

2. **AMDF Activities report – 2021**

Presenter: Paulyne Wairimu - AMDF

The Vice Chair reminded members that AMDF is a technical committee under the umbrella of the AMRH governance framework with established Terms of Reference. In 2021 AMDF conducted several capacity building activities for regulators in Africa through collaborations with Saudi FDA which is a WHO collaborating Centre. In February 2021, four-days' workshop on Technical file assessment for Medical Devices including COVID-19 was conducted and over 100 technical experts were trained. In November 2021 a second workshop on Post Market surveillance and market surveillance workshop was conducted with over 120 regulatory experts trained. AMDF has also set up an online self-learning module for regulators who work at their own time and so far, 114 regulators have attended the course.

The three sub-WGs have so far developed four guidelines (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 which were approved at the 9th AMRH Steering Committee meeting. Six (6) draft guidelines are currently being reviewed and will be submitted once consensus is reached. AMDF has been working with several partners including USP to develop AMDF 5 year Strategic Plan which has been reviewed and a final copy will be made available. The recommendations from the strategic plan have been set up as objectives for the 2022 workplan.

3. **Draft AMDF work plan for 2022**

Presenter: Dimakatso Mathibe - AMDF

Ms Dimakatso from SAHPRA presented the draft AMDF 2022 planned activities which are based on four main objectives. The first objective is to aadvance and promote African continent harmonization, mutual recognition, and reliance of medical devices regulations in Africa. The second objective is to 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. The third objective is to advance the sensitization, adoption and roll out of AMDF strategic priorities across member states, partners, and stakeholders. The last objective is to continue to build technical capacity of national regulatory agencies in medical devices and IVDs regulatory frameworks, guidelines, and quality management systems. These objectives are based on the draft AMDF 5 years strategic plan. The various activities within the objectives are being discussed and will be shared once finalized.

4. **AMDF 3 Year Plan (2029-2021)**

Presenter: Paulyne Wairimu - AMDF

Paulyne presented on the progress report for the AMDF for the three years since the last meeting of the AMRC at Victoria falls in Zimbabwe. In the three years, AMDF has established the three sub working groups (pre-market, on market placement and post market surveillance. Membership for these three groups is drawn from nominated experts from the national regulatory authorities through the regional economic communities. In response to the COVID-19 pandemic, AMDF constituted a taskforce which was established on 20th March 2020, made up of experts from NRA's in Africa, WHO, partners and laboratory experts. The deliverables for these four groups includes regular preparation of lists of COVID-19 diagnostic assays and priority medical which were approved for use during the pandemic, SOPs for reporting substandard and falsified medical devices and IVDs as well as a Medical Device Donation Guidelines.

The first virtual technical committee of the AMDF was held in July 2020 in which discussed, AMDF Terms of Reference, responsibilities of each sub working group and workplan for year 2020. The meeting also elected leadership of the three sub Working groups (Chair and Secretary) for operationalization of the sub working group; iii. It also discussed 2019 survey report on regulatory landscape in Africa based and provide recommendations. Lastly, the TC developed action plan and next steps for each sub working group.

5. **Draft Five years AMDF Strategic Plan (2022 -2027)**

Presenter: Mr Mwemezi Ngemera - USP

Ngemera presented the draft AMDF 5 years strategic plans which is being developed in collaboration with AMDF. He started by explaining the process which was followed to develop the plan. The plan consists of six strategic priority areas. The first strategic priority is to support the establishment and operational implementation of the Africa Medicines Agency. The second strategic objective is to advance and promote continental harmonization, mutual recognition, and reliance of medical devices regulations. The third strategic priority is to promote innovation and local manufacturing of quality-assured medical devices and in-vitro diagnostics in the continent. Strategic priority 4 is to strengthen partnerships for advocacy on strengthening medical device regulation at continental level and priority countries. The fifth strategic priority is to build technical capacity of national regulatory agencies on medical devices and IVDs regulatory frameworks, guidelines, and quality management systems. The sixth strategic priority is to facilitate the registration, promote validation, and joint activities and post marketing surveillance related to quality, safety and efficacy of medical devices and IVDs in the continent. Finally, he listed the next steps which will include solicitation of comments from all AMDF members and non-member NRAs, finalization and resource mobilization

6. **Technical update: WHO`s update on medical devices including in vitro diagnostics**

Presenter: Agnes Kijo - WHO

Ms Agnes Kijo presented on the recent WHO efforts to strengthen regulation of medical devices including efforts to improve rapid access of medical devices in a timely manner. They include WHO collaborative procedure for prequalified IVDs. In addition, WHO in collaboration with UNITAID have been conducting workshops with STAR Phase 3 countries for HIVST including Tanzania, Cameroon, Mozambique, Uganda, Indonesia and India with the objective of creating awareness on the benefits of the CRP in accelerating marketing authorization of new IVDs. This has led to an increased number of CRP of countries from 3 in the pilot phase to 13 countries**.** WHO has also introduced risk-based approach mechanism for WHO EUL in vitro diagnostics similar to the WHO Collaborative Registration Procedure designed for WHO Prequalified medical products.

She further reported that currently, the WHO Global Model Regulatory Framework for Medical Devices including IVDs which was published in 2017 is being revised to include recent developments and align with other recent WHO guidance including the one on post market surveillance and market surveillance; Good Regulatory Practice; Good Reliance Practice and Global Benchmarking tool plus medical devices.

7. **Towards standardized nomenclature of medical devices**

Presenter: Adriana Velazquez, Team lead medical devices - WHO

Adriana started her presentation by explaining WHO goal which is better health care and patient safety through use of nomenclature which will ensure improved access of safe, quality medical devices. She reported list of WHO Publications of priority medical devices and essential in vitro diagnostics and related technical specifications of quality and safety to be available, affordable, acceptable, appropriate. She informed the meeting that Member States have requested WHO to work on standardization of nomenclature for medical devices which should be transparent, harmonized and evidence based, open systems to be accessible for all. Lastly, she elaborated on the ongoing consultation on the subject.

8. **Technical Update: European Union Medical Device Regulation and In Vitro Diagnostic Medical Device Regulation**

Presenter: Willy Urassa, Independent Consultant - WHO

Willy started by explaining the changes which have been implemented in the regulation of medical devices after approval of EU Regulation on medical devices and EU Regulation on in vitro diagnostic medical devices in 2017. He listed some of the improvements which include stricter premarket and post market requirements which may affect manufacturers and conformity assessment bodies. For manufacturers there will be increased costs, commercialization delays, and device removals while for smaller companies will likely be pushed out of the market due to inability to comply with the MDR by the date of application, lack of resources, time constraints, or both. Lastly companies will likely have to make difficult strategic decisions to prioritize certain products. Regulators were encouraged to prepare contingency plans in case of reduced or delayed supply, withdrawal of product and possibly circulation of inferior goods.

9. **Recommendations to the AMRC**

The following are AMDF recommendations to AMRC:

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

10. **Election of the AMDF leadership**

The meeting was informed that after serving for three years as per the TOR, there will be election of new leadership. Further informed that regulators were invited to express interest to be take the post. There was one applicant for the post of Chair and two applicants for the Vice Chair. The election was conducted after fulfilling the requirements. Paulyne Wairimu from PPB Kenya was elected the Chair while Dimakatso Mathibe was elected the Vice Chair of AMDF. As there were no applicant for the Rapporteur, it was agreed that they position will be filled later.

11. **Closing remarks**

The new Chair and Vice Chair thanks the participants for the trust they have shown. They promised to work together to strengthen the work of AMDF

12. **Annexes**

12.1 Final program
12.2 Presentations