

15:25 – 15:40

African Medical Devices Forum (AMDF)



Dimakatso Mathibe

Vice Chair, African Medical Devices Forum (AMDF)







African Medical Devices Forum

International Medical Device Regulators Forum Stakeholder Open Forum

Dimakatso Mathibe AMDF Vice-chair/SAPHRA SA

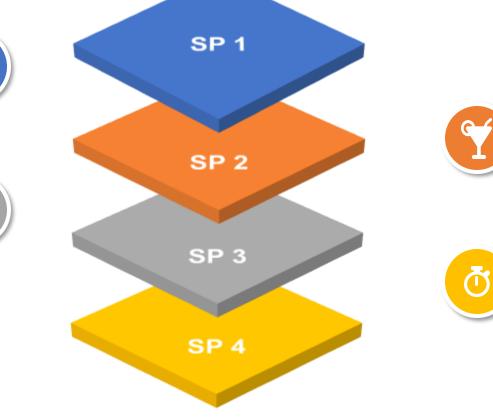
Brussels, Belgium 27 March 2023

AMDF Workplan 2023

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

Advance the sensitization, adoption and roll out of AMDF strategic priorities across member states, partners, and stakeholders

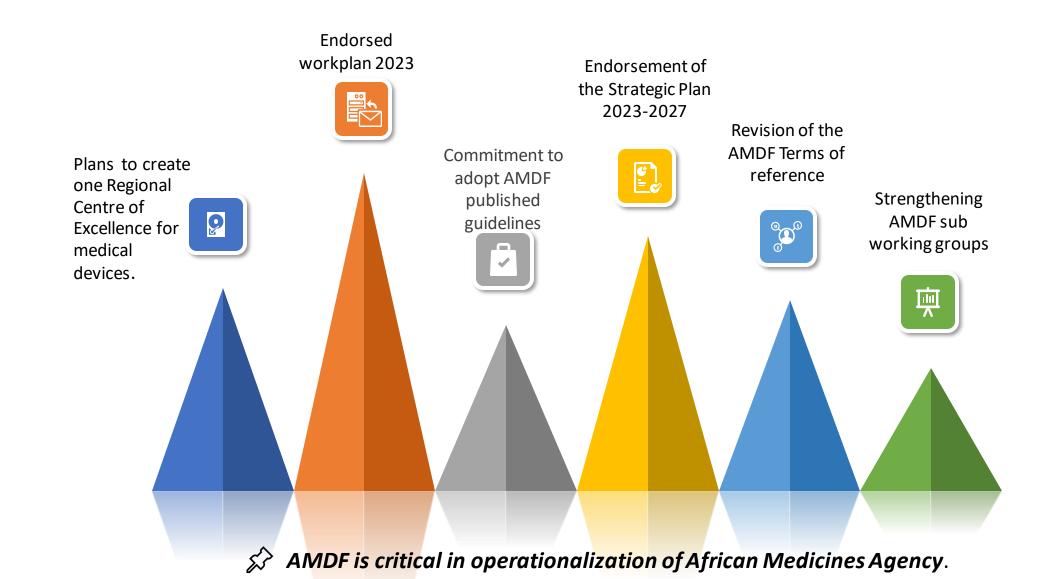




Encourage innovation in medical devices including invitro diagnostics on the continent through local production of quality-assured essential medical devices and in-vitro diagnostics as sustainable path in ensuring self-reliance

Continue to build technical capacity of national regulatory agencies in medical devices and IVDs regulatory frameworks, guidelines, and quality management systems

AMDF Technical Committee meeting in Accra, Ghana 6-7 December during AMRH week



Planned output 2023

1

Finalization AMDF guidelines on EUL, FSCA. Labelling, Listing and MNCH medical devices (companion document).

3

Training (materials for assessment of technical files, assessment of training needs and strategy on twinning).

4

Strategic plan on local production of medical devices

Based on AMDF Strategic Plan 2023 - 2027

2

Stakeholders inventory

Partner/Stakeholder support to AMDF

 \Rightarrow AMDF is a key asset in the development of technical expertise for the AMA.

Partners - WHO, MTaPS, FIND, ASLM, MDRC, USP - confirmed support for the strategic priorities of AMDF.

 \Rightarrow Partnerships are being explored specifically with mature NRAs.

A Participation and alignment with global harmonization initiatives e.g. GHWP

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Thank you!

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