

AFRICA MEDICAL DEVICES FORUM

PAULYNE WAIRIMU

Chair: AMDF

26th September 2023
IMDRF Management Committee
Open Session

African Medical Devices Forum

AMDF Leadership



Chair: Paulyne
Wairimu (Kenya)



Vice- Chair:
Dimakatso
Mathibe
(South Africa)

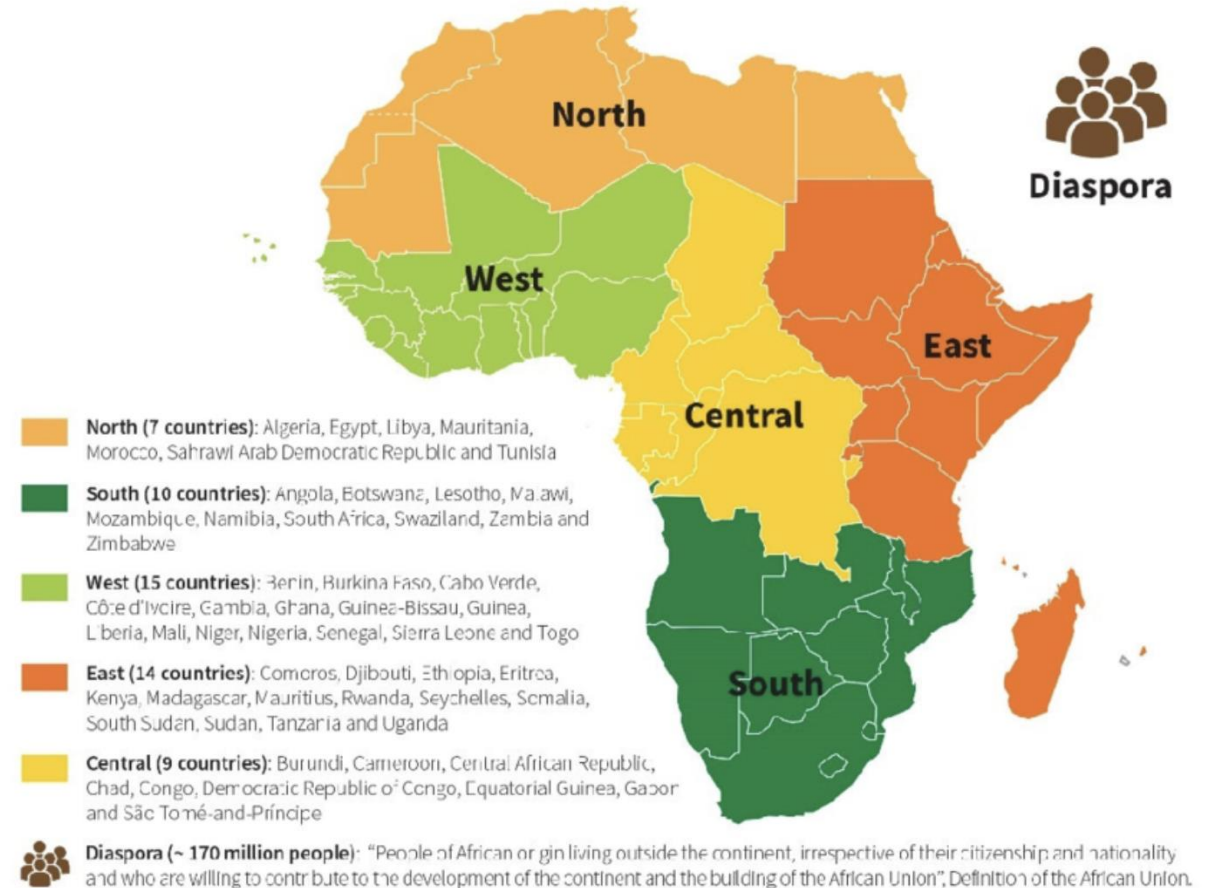


Rapporteur:
Frank Laban
(Zambia)

AMDF Membership

- ✓ Kenya
- ✓ South Africa
- ✓ United Republic of Tanzania
- ✓ Zanzibar
- ✓ Zambia
- ✓ Botswana
- ✓ Uganda
- ✓ Rwanda
- ✓ Burundi
- ✓ Ethiopia
- ✓ Nigeria
- ✓ Ghana
- ✓ Senegal
- ✓ Congo
- ✓ Namibia
- ✓ Zimbabwe
- ✓ Morocco
- ✓ Egypt

THE SIX REGIONS OF THE AFRICAN UNION



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AMDF ACTIVITIES

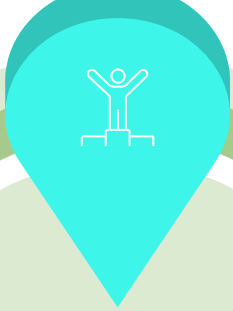
Harmonization

January-23
GHWP Riyadh meeting,
Increase membership
for AMDF to GHWP for
harmonization



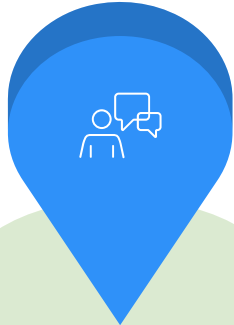
AMRH-SC

April and June -23
Submission of developed
resources to
maternal/newborn and
child health



Supporting Local Manufacturing of Diagnostics

August-23
The establishment of
the African initiative
for Diagnostics
access



Building

Utilization of the Virtual
platform for capacity
building initiatives.
Physical workshop
planning ongoing



WHA

June-23 Adoption of the
resolution supporting
diagnostics access to
African member states



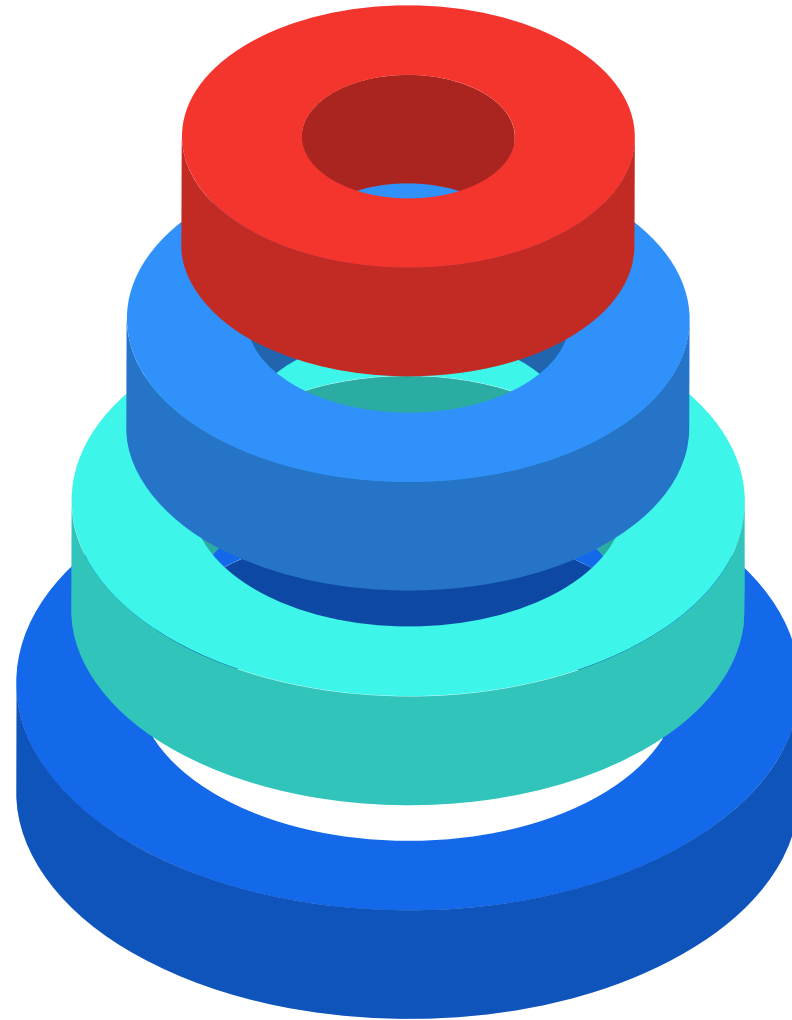
Areas of Focus-

Operationalization of Africa Medicines Agency

-AMDF- Resource to the Operationalization of the African Medicines Agency
-AMDF Attended the biannual meeting in June with a view of aligning the workplan with the continental initiative

Capacity Building

Domestication and uptake of the developed resources, which include guidance document on Market authorization, Control of Import &Exports, Quality audits and registration of establishment of medical devices.



Maternal, Newborn and Child health Guidance Document Development

With the support of Partner, -AMDF Developed a resource to support in regulating maternal, newborn and child health sub population medical devices
-The use of IMDRF Guidance document as a resource.

Enabling Access to Resource for Medical Devices to Regulators

Developed resources are made available to national regulatory authorities with a view of accelerating access.

AMDF-RHI-IMDRF



Regional Harmonization

-Elevate the standards of Documents that NRA's use for conformity, enabling Access and Removing Barriers

Capacity Building and Technical Knowhow Exchange

-Africa has its set of challenges that when shared make regulatory harmonization efforts



Information Sharing



-Platform for information sharing on Opportunities, Challenges and Areas of collaboration
-Fostering an environment for responsive regulatory practices

Keeping abreast with Current Practices



Fostering an environment where we are able to keep abreast with new information, technologies and practices in the regulation of Medical devices and Diagnostics.

Thank you/Asante Sana

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