Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

World Health Organization

Africa Medical Devices Forum

International Organizations & Harmonization Efforts

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12th December 2024

Outline

01 Background – AMDF Objectives

02 Global Convergence and Reliance

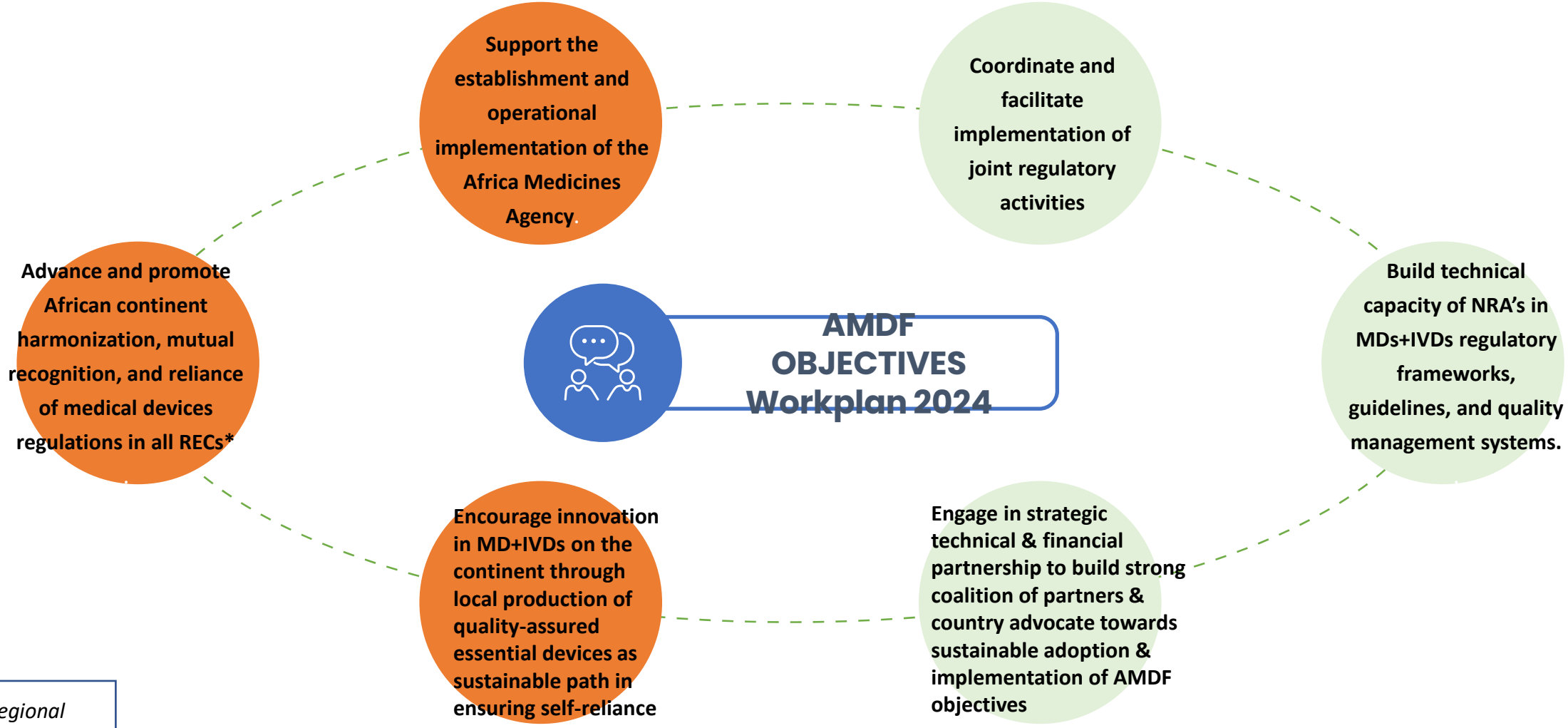
03 Structural arrangement – AMDF, MDA-TC

04 Continental Overarching Procedure

05 Looking Ahead

AMDF STRATEGIC OBJECTIVES

AMDF Workplan 2024



Rec-regional economic committee

AMDF-Global Convergence

Through Advocacy and use of International Platforms to advance Harmonization of Medical devices in Africa

African Medicines Agency

Supporting the operationalization of AMA

A M R H

Supporting the Operationalization of AMA

MDA-TC Committee

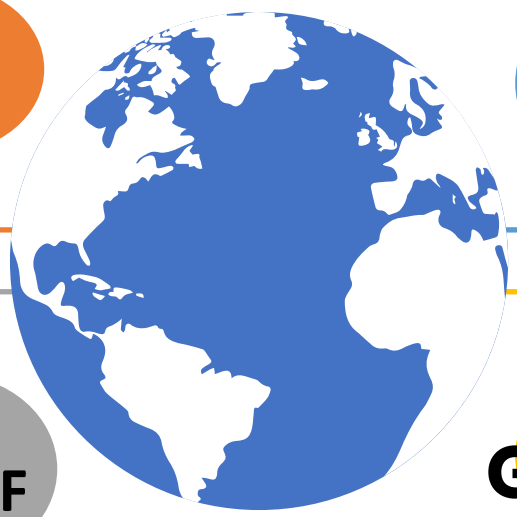
WHO

Reliance and WHO Standards in Medical Devices Regulation

WHO-CRP Program

ICDRA

PQ-assessment of In-Vitro Diagnostics



IMDRF

Regional Harmonization Initiative (RHI)

Affiliate Memberships -Technical Access and participation

GHWP

Collaboration and Harmonization

Increased Membership

Reorganization of AMRH Medical Devices Regulatory Workstream & the African Medical Devices Forum (AMDF)

Coming into force for the Treaty of the African Medicines Agency (AMA) led reform and repositing of current AMRH structures especially Technical

including the AMDF for the purpose of supporting the operationalisation of the Agency and the emerging Africa regulatory ecosystem

The restructuring is composed on 3 key elements

- Stepwise implementation: Prioritization of continental regulatory functions
- Establishing regional Medical Devices Regulatory Frameworks: Stepwise approach
- Separation of Forums from Technical Committees to allow the undertaking of continental joint regulatory work and inclusion of All AU member states

The MDA-TC
Inaugurated during 1st MDA-TC Meeting 28/10/24 Maputo Mozambique

-19 Member Committee
-Representative of the 8 RECs
-Drive the Continental

Objectives & Components of the Continental Regulatory Framework for IVDs

- Provides for a continental Overarching Procedure for evaluation and listing of priority Invitro Diagnostics (IVDs)
- Guide the establishment of pool of experts (evaluators, quality auditors or inspectors) and multi-national evaluation teams for medical devices – Focusing on IVD's
- Guide on technical requirements and guidelines for evaluation and listing of priority IVD's.
- Provides Tools for implementation of the Continental Regulatory Procedure of IVDs listing – (i.e, Compendium of Guidelines, Templates and SOPs) – WHO primary reference, IMDRF etc (AMDF Guidelines)
- Guide on Operational Relationship between AMRH (AMDF, MDA-TC)

KEY STAKEHOLDERS AND STRUCTURE

Main Bodies Involved:

- AMA & AMRH: Oversight and Policy integration
- MDA-TC: Primary evaluation and technical committee for IVDs
- National Regulatory Authorities (NRAs): In-country implementation of MDA-TC recommendations

Supporting Entities: AUDA-NEDAP, WHO and Regional Economic Communities (RECs)

Looking Ahead

- Continental Process Harmonization , Collaboration and Reliance Practices
- Global Regulatory Convergence, and Reliance
- **Advocacy and participation**

Thank you