For A Healthier Africa
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From Regional Efforts to Continental Impact Harmonization in Action

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Agenda

Introduction

National Regulatory Authorities (NRAs) have very uneven capacity. Some countries have strong regulatory frameworks, others have minimal or fragmented oversight for medical devices/IVDs.

Fragmented regulation means more administrative burden, redundant testing, inspections, etc. Harmonization & mutual recognition can reduce duplication, lowering cost and time

If regulatory approval is unpredictable, slow, or costly, manufacturers may not bring needed devices/IVDs to certain countries. Harmonization can reduce duplication of effort (e.g., one dossier accepted in multiple countries), speed up approvals, make supply more reliable.

Vision for a Unified Regulatory Landscape:

Efficient regulatory pathways and Transparent, predictable, accountable regulation

Background: Fragmented Beginnings

Issue	Impact
Fragmented regulatory systems	Delays, high costs, confusion
Manufacturers face duplication	Increased time-to-market, higher compliance costs
Regulators overburdened	Inefficient use of limited resources
Patients & providers lose out	Slower access to quality devices
Lack of trust & transparency	Risk of unsafe or ineffective products

Africa urgently needs greater regulatory harmonization and convergence

Regional Efforts: Building Blocks of Harmonization

Initiative	Focus	Achievements	Challenges
EAC-MRH	Medicines (expanding to devices)	Joint assessments, shared guidelines	Legal misalignment, uneven capacity
WA-MRH	Medicines & IVDs (guidelines in draft)	Drafting regional device guidelines	Language barriers, capacity gaps
ZAZIBONA	Medicines	Model joint assessment process	Not yet extended to devices
SADC Framework	Regional alignment	Supports ZAZIBONA, regulatory capacity	Requires more device focus
ECCAS & IGAD	Early-stage	Dialogue and early coordination	Limited progress on devices
ECOWAS Device Guidelines	Medical devices & IVDs	Drafting regional regulations	Finalization and implementation pending
RECs (overall)	Political and technical coordination	Drive harmonization	Capacity gaps, enforcement of decisions

Continental Momentum: African Medicines Agency (AMA)

AMA is the enabler of continent-wide regulatory harmonization

- Harmonize and coordinate medical product regulation across African Union member states.
- Facilitate mutual recognition and reliance between National Regulatory Authorities (NRAs).
- Strengthen regulatory systems by supporting capacity building

African Medical Devices Forum (AMDF)

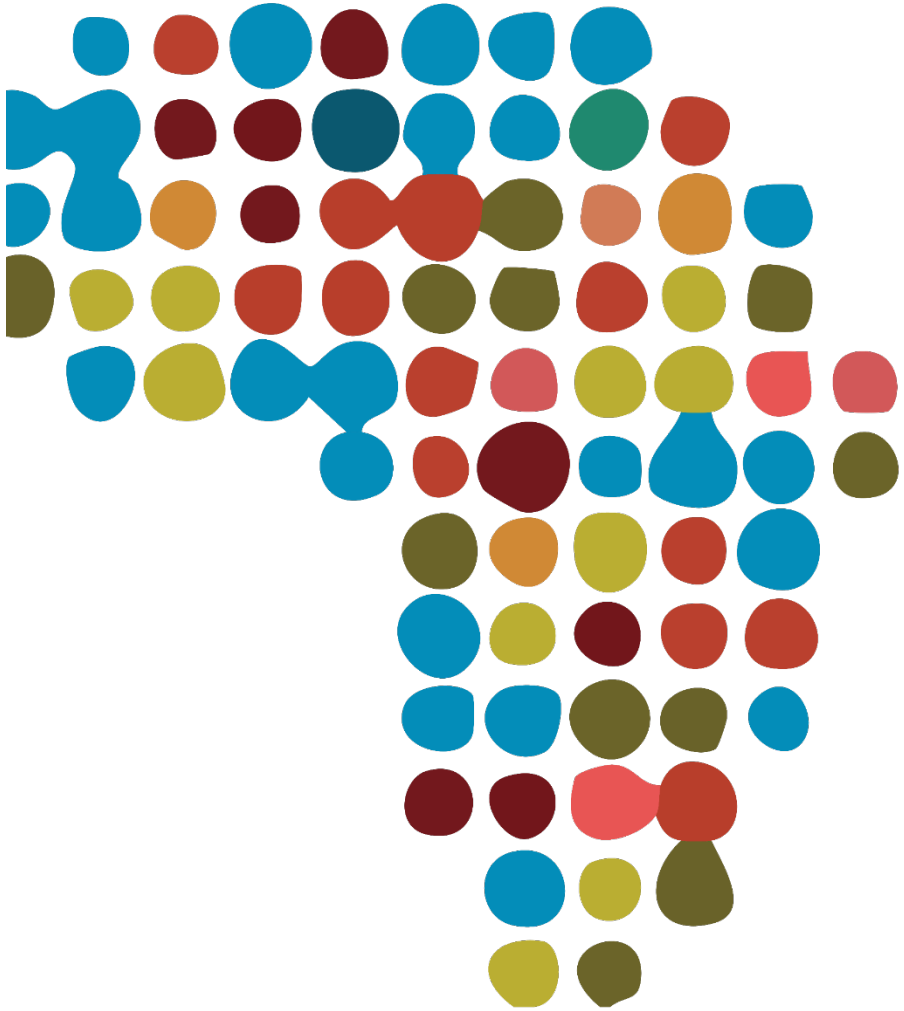
- ❑ Facilitate dialogue between National Regulatory Authorities (NRAs), regional bodies, and global stakeholders on medical device/IVD regulation.
- ❑ Promote the harmonization of regulatory requirements, such .
- ❑ Support the development of guidelines, frameworks, and tools for medical device regulation in Africa.
- ❑ Provide technical guidance and capacity building to strengthen national systems.

Medical Devices and Diagnostics Technical Committee (MDA-TC)

- ❑ Developing continental guidelines and standards.
- ❑ Recommending risk-based classification systems.
- ❑ Supporting convergence in conformity assessments, registration, and post-market surveillance.
- ❑ Acts as a technical advisory group to AMA on medical devices and diagnostics.

Diagnostic advisory committee (DAC)

- ❑ Advising on diagnostic performance evaluation.
- ❑ Supporting diagnostic prioritization during health emergencies.
- ❑ Strengthening continental capacity for IVD assessment.



Impact and Benefits

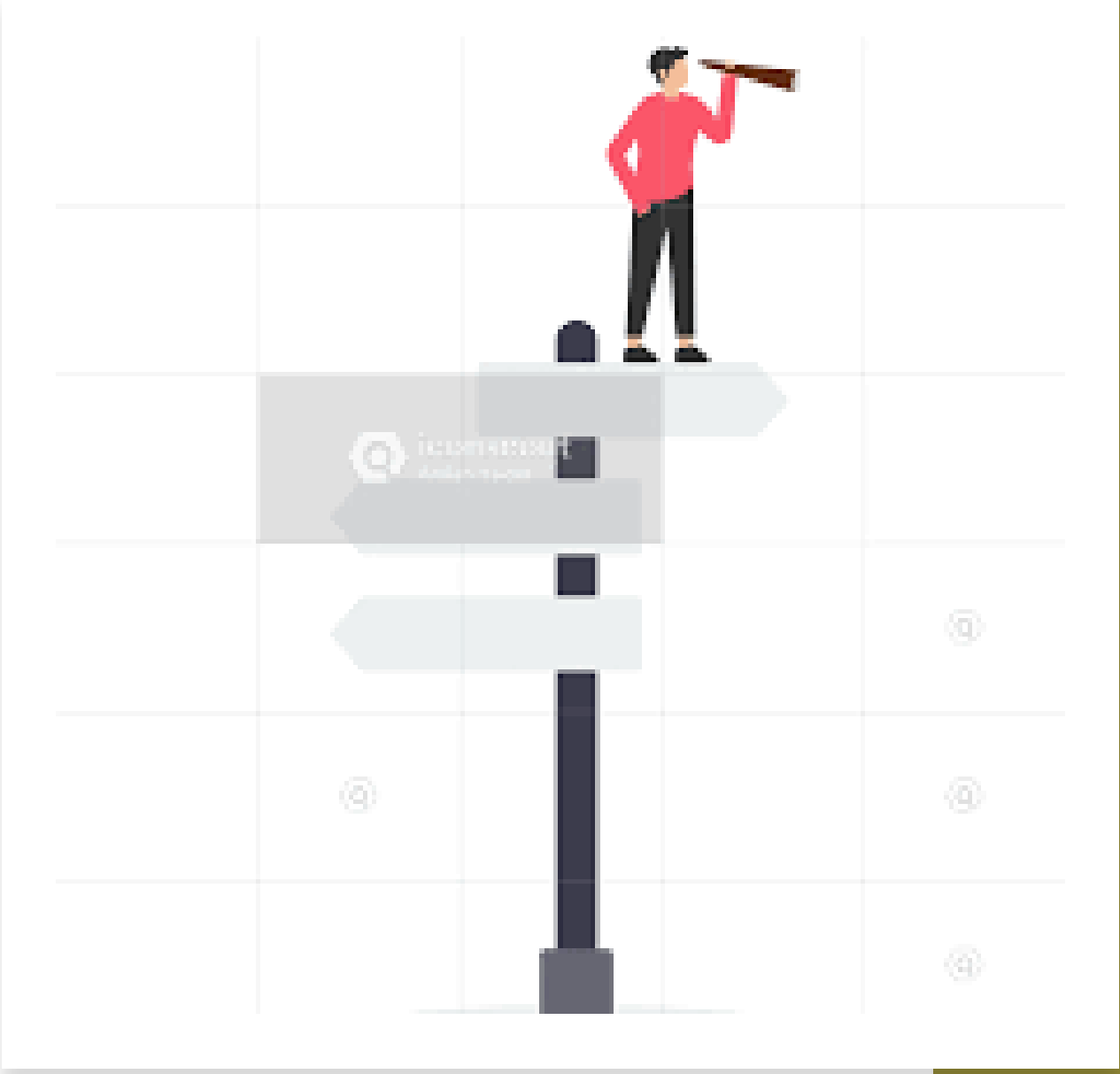
- Faster access to safe and high performing medical devices
- Efficient use of regulatory resources
- Increased confidence among industry and global partners
- Strengthened regulatory capacity and collaboration
- Public health outcomes and emergency response readiness (e.g. COVID-19, Ebola, mpox

Challenges and Considerations

Challenge	Details	Considerations for Success
National sovereignty vs. continental alignment	Balancing autonomy with shared decisions	Foster trust, clear protocols, political will
Legal and policy alignment	Diverse and outdated legal frameworks	Develop model laws, provide technical support
Resource constraints & sustainability	Funding, skills, infrastructure gaps	Innovative financing, capacity building, partnerships
Equity among NRAs	Disparities in capacity and influence	Prioritize assistance, regional centers, inclusive governance
Language & infrastructure barriers	Multilingual challenges, limited digital tools	Multilingual platforms, digital investments, training

Looking Ahead: Sustaining the Momentum

- **Looking Ahead: Sustaining the Momentum**
- Full operationalization of the AMA
- Strengthening regional platforms to feed into AMA
- Integration of digital regulatory systems across countries
- Monitoring progress through measurable indicators
- Emphasizing political commitment and stakeholder buy-in



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HARMONIZATION IS NO LONGER AN ASPIRATION BUT A REALITY IN PROGRESS

FROM REGIONAL PILOTS TO CONTINENTAL FRAMEWORKS AFRICA IS SHAPING ITS REGULATORY FUTURE

CONTINUED COLLABORATION IS ESSENTIAL FOR LASTING IMPACT ON PUBLIC HEALTH AND INNOVATION

THANK YOU