



Global Harmonization Working Party

Towards Medical Device Harmonization

Regulatory Convergence and Reliance in Africa

Sharing good Practices

28th GHWP Annual Meeting and 28th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur, Malaysia

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Outline

- AU-Model Law- Legislative Reforms in the Continent
- African Medicines Agency (AMA)
- Regulatory Convergence- Regional Harmonization Initiative to IMDRF
- Guidance documents Harmonization
- Medical Devices Assessment Technical Committee (MDA-TC)
- Key Takeaways

AU Model Law on Medical Products Regulation



The African Union (AU) Model Law is a legislative framework that addresses these challenges by harmonizing requirements and processes as follows:



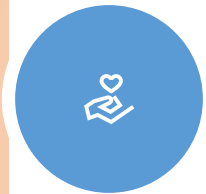
Au-model Law-Medical Devices Including In-vitro Diagnostics-AMA Treaty



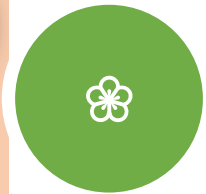
55 Member States
8 RECs
1 AMA



Executive Council Decision: [AU Executive Council Decision, {EX.CL/Dec.857 \(XXVI\)}](#) of January 2015). The African Medicines Regulatory Harmonization (AMRH), a foundation for AMA

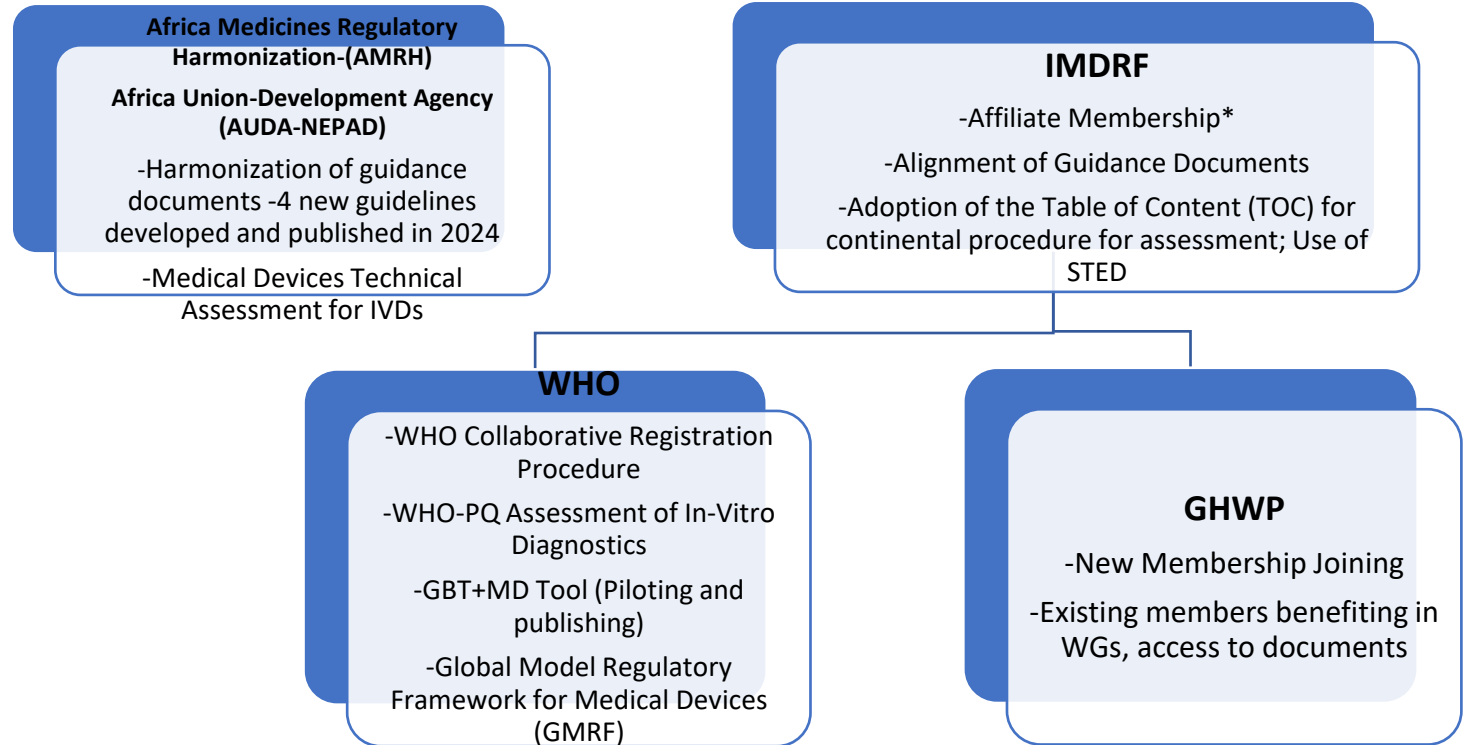


Medical Devices Including In-Vitro Diagnostics
-Definition according to the IMDRF (Previously GHTF on definition of the term Medical devices, WHO-GMRF



Medical Products definition
Means medicines, Vaccines, Blood and Blood products ,Medical Devices and Diagnostics

Regulatory Convergence and Reliance-Regional Harmonization Initiative(RHI)



*Botswana, Egypt, Ethiopia, Kenya, Nigeria, South Africa, Tanzania, and Zimbabwe (Current member-Sept 24)

AMDF REORGANIZATION

AMDF as a Forum: Consist of medical device registration/regulatory officers/heads from AU member states

Medical Devices Assessment Technical Committee (MDA-TC): A technical arm under the AMDF comprised of medical devices assessment experts from AU member states nominated through the regional economic communities (RECs)

AMDF
Forum


Strategic, advocacy and facilitating in country adopting of decisions taken at continental level

MDA TC

- scientific evaluation and assessment of selected medical devices, IVDs and technologies
- scientific opinion on the quality, safety, and performance of devices development of technical guidelines and standards
- capacity building to NRA staff from the member states.

Using Reliance in Responding to Monkey-Pox(M-pox) Health Emergency

AMDF reformed to establish a technical arm (i.e. the MDA-TC) – Held its inaugural meeting 28-29 Oct 2024




Developed Continental tools for responding to Mpox

continental standard operating procedures

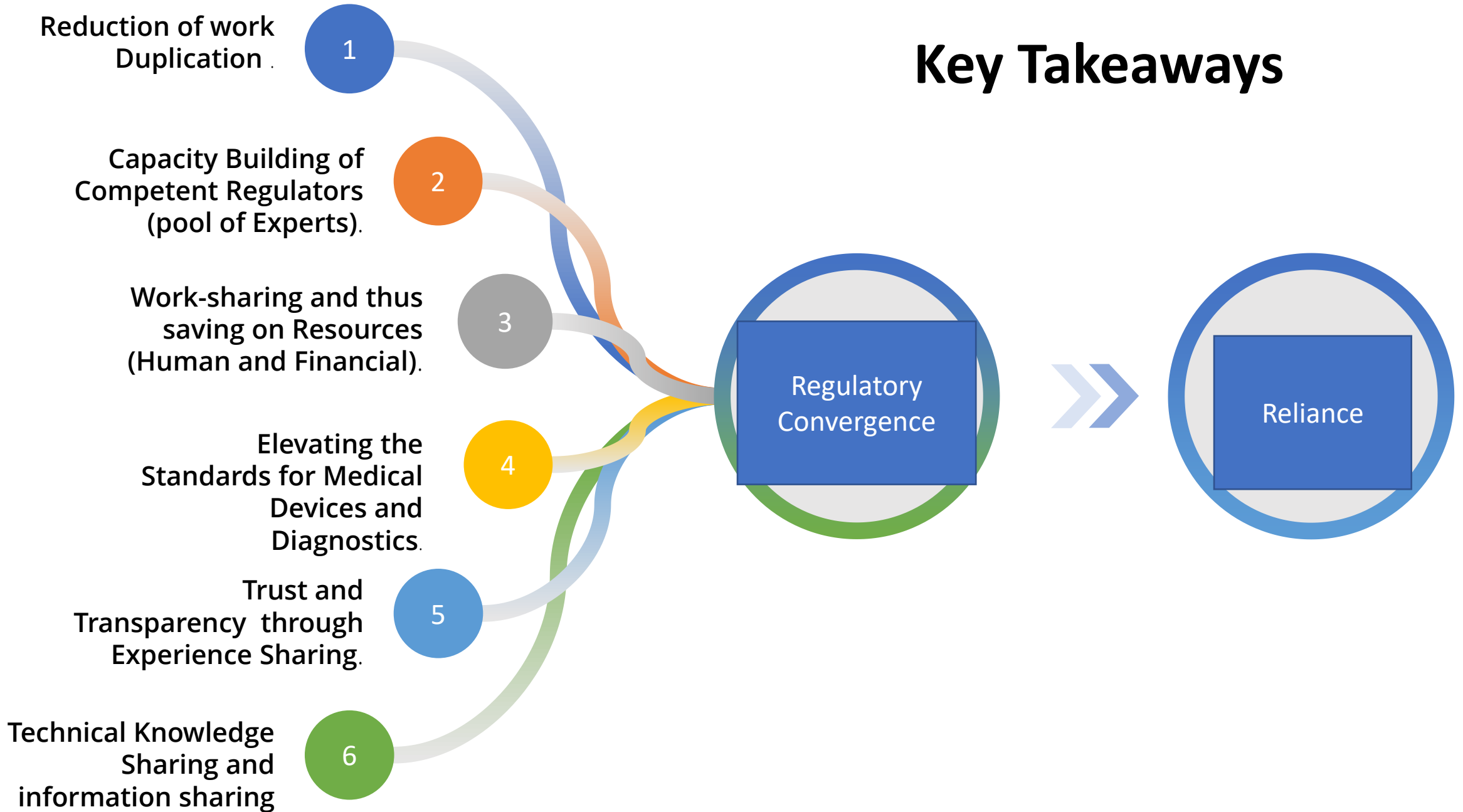
Templates for Evaluation of IVDs New, Renewal and Variations and a Public Assessment Template

Guidance for assessments based on the IMDRF of the ToC



Current considering the Overarching Continental Procedures to be piloted next year (starting Q1, 2025)

Key Takeaways



**Thank you
Asante Sana**

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