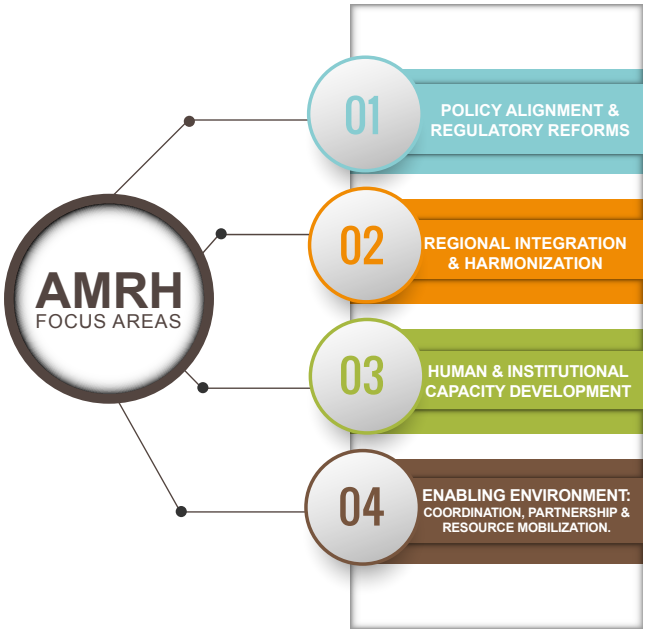
AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

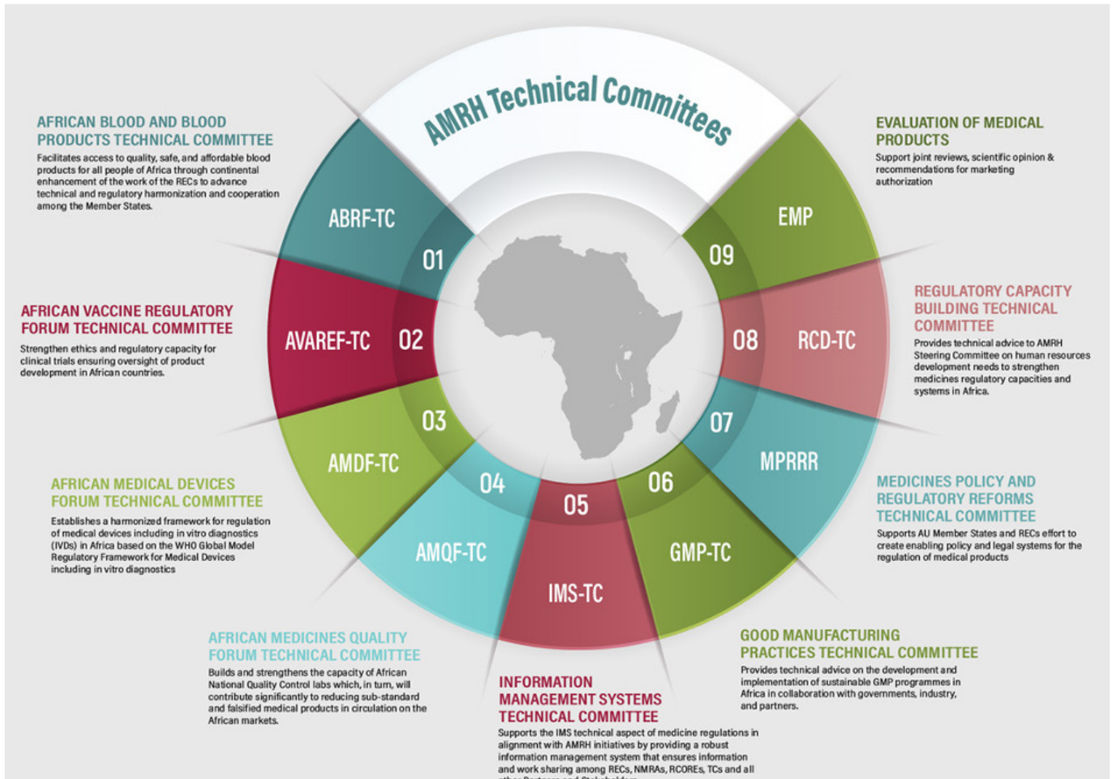
Paving the Way for African Medicines Agency

The Pharmaceutical Manufacturing Plan for Africa (PMPA) envisions an Africa where there is significantly reduced reliance on pharmaceutical imports and reduced proliferation of sub-standard and falsified (SF) medical products on the continent. To contribute to the PMPA agenda, the African Medicines Regulatory Harmonization (AMRH) initiative was established through the African Union Development Agency-NEPAD (AUDA-NEPAD), in 2009 and first launched in the East African Community (EAC) in 2012. Community of West African States (ECOWAS) , the Southern African Development Community (SADC), as well as the Intergovernmental Authority on Development (IGAD) and the Central African Economic and Monetary Community (CEMAC).

The AMRH initiative places emphasis on aligning technical and procedural guidelines for the registration of medicines, diagnostics, devices, vaccines, blood, and blood products. Its scope extends to Good Manufacturing Practice (GMP) inspections, quality management systems, clinical trial oversight, safety monitoring of medical products, and regulatory information management systems. This comprehensive approach operates within a multistakeholder governance framework, fostering critical partnerships with National Medicines Regulatory Authorities (NMRAs), Regional Economic Communities (RECs), and development partners.



PATH



The RECs implementing AMRH have significantly improved their NMRAs capabilities to authorise medical products for the market. Harmonised regulatory technical requirements and procedures have also been agreed upon and are being utilised at both regional and national levels. Additionally, NMRAs actively participate in joint dossier assessments, which have demonstrated considerable success in improving access to medical products in their respective regions and countries.

The journey towards a single continental African Medicines Agency (AMA) gained momentum with the entry into force of the AMA Treaty in November 2021. Fifteen countries fully ratified and deposited their instruments of ratification with the African Union Commission (AUC), signalling commitment to the AMA's vision. Subsequently, 12 additional countries have ratified the Treaty, bringing the total number of AMA State Parties to twenty-seven (27) as of January 2024.

Key achievements of the AMRH

1. **Establishment of Continental Technical Committees:** These committees drive the development of inter-regional and continental standards, processes, and coordination in crucial areas as evaluation of medicinal products, GMP inspections, capacity development and strengthening, policy and regulatory reforms, vaccine and medical device regulations, as well as medicines quality.

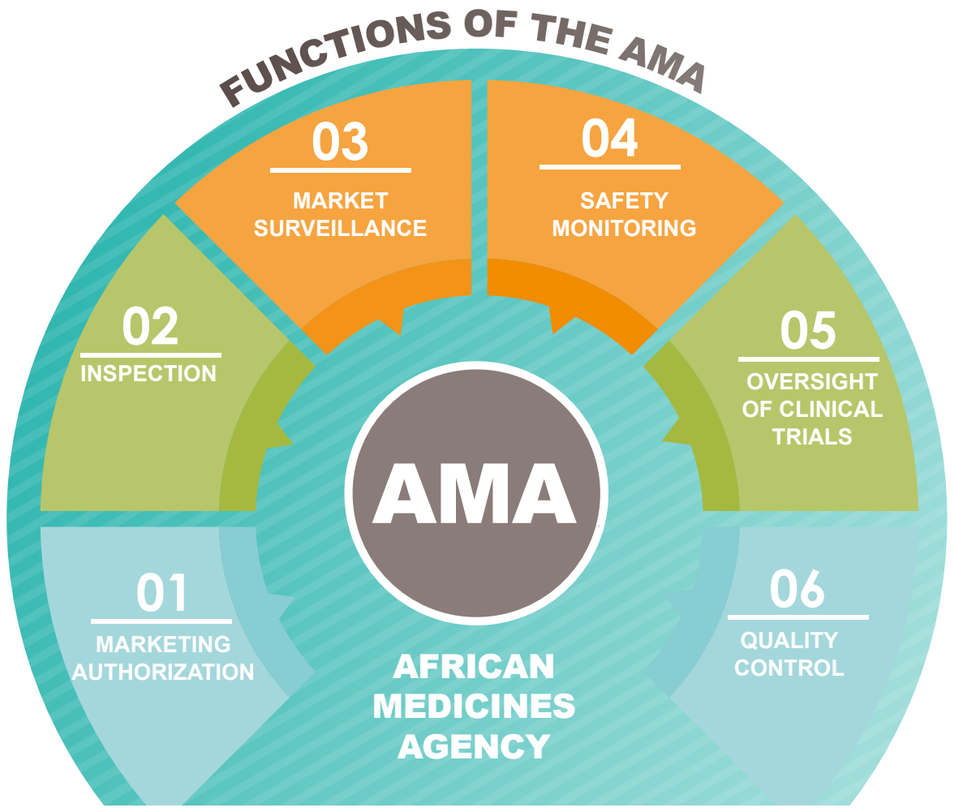
2. **Coordination of Regional Harmonisation and Joint Regulatory Work:** AMRH facilitates regional joint assessments within the RECs, demonstrated through successful, long-standing initiatives such as Zazibona, which is implemented through SADC. Additionally, it fosters the adoption of regional standards and guidelines in the RECs.

3. **Establishment of Regional Centers of Regulatory Excellence (RCOREs):** Enhancing regulatory capacity is recognised as a fundamental pillar, with potential far-reaching benefits across various regulatory initiatives. To ensure effective medicines regulation, expertise in medicine regulatory science is paramount. Eleven (11) RCOREs were established by the AMRH since 2014, with the designation of four (4) new RCORES for Vaccine Regulatory Oversight in 2023.

4. **Collaborative Structures:** AMRH promotes collaboration among NMRAs, particularly focusing on those achieving World Health Organization (WHO) Maturity Level 3 (ML3). This collaboration facilitates work-sharing, reliance models, and regulatory harmonisation.

5. **Partnership Platform:** A formalised platform that brings together regulatory institutions, civil society, and partner organisations to coordinate support on regulatory systems strengthening, harmonisation, and the operationalisation of AMA. The AMRH Partnership Platform serves as the African Chapter of the WHO Coalition of Interested Parties.

6. **Strategic Planning:** AMRH has developed a 5-year action plan to effectively harmonise technical systems in support of the operationalisation of AMA.



The COVID-19 pandemic underscored the urgent need for local production of essential medical products. Regrettably, many NMRAs were inadequately equipped to handle the heightened regulatory demands posed by the pandemic. Insufficient human resources, funding constraints, and incoherent policies hindered their ability to respond effectively. AUDA-NEPAD, through the AMRH initiative, stepped up to address these challenges, providing technical support to member states and facilitating the domestication of the African Union Model Law on Medical Products Regulation. The domestication of the AU Model Law is critical for enabling countries to uptake the recommendations that AMA will provide.

The benefits of the AMA are multifaceted; it will streamline regulatory systems, expediting the approval and authorisation of medical products. It will foster research and development within Africa, enabling the development of medical products and vaccines, thereby mitigating the impact of future public health emergencies. The AMA will also strengthen the capacity of RECs and NMRAs to share regulatory information, combatting the illegal entry of substandard and falsified medicines into markets. As local manufacturing gains momentum, trade will inevitably increase, contributing to the successful implementation of the Africa Continental Free Trade Area (AfCFTA). This has the potential to lift millions of Africans out of poverty.

AMA will therefore enhance and complement the efforts of NMRAs, while contributing to capacity building towards improving access to quality, safe, and efficacious medical products. While the AMA Governance Board will offer strategic direction informed by scientific advice from continental technical committees, it will not directly authorise products for the market as this mandate will remain with the NMRAs.

The AUC and the AUDA-NEPAD play key roles in shaping the continent's healthcare landscape. The AUC provides policy and administrative leadership for AMA with technical support from AUDA-NEPAD. This collaboration demonstrates the concerted effort to enhance healthcare and expedite access to life-saving medicines.

The knowledge and expertise acquired through the implementation of the AMRH initiative must not be overlooked; instead, it should be leveraged to strengthen the operational phase of the AMA. As AMA takes on a more prominent role in coordinating regulatory systems strengthening and harmonisation in Africa, AUDA-NEPAD will continue to play a significant supporting role until all AU member states are party to the AMA Treaty.