Implementing the African Union Model Law at the Regional and National Level

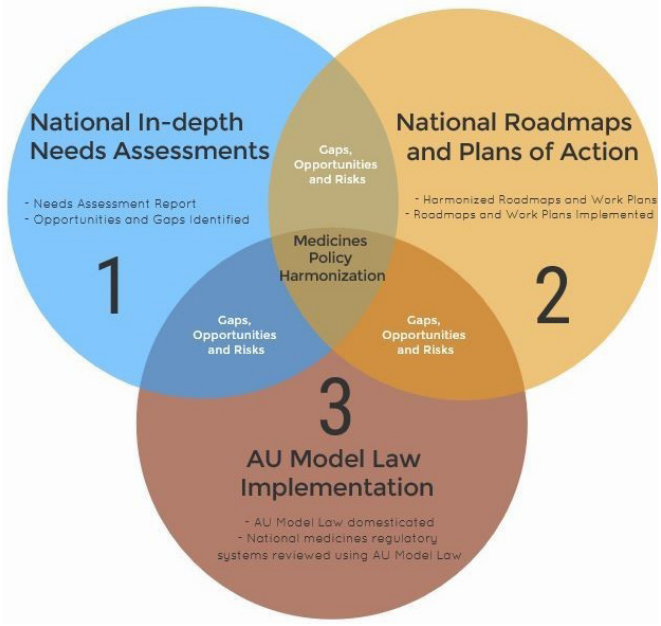
INTRODUCTION

Following the endorsement of the *African Union (AU) Model Law on Medical Products Regulation* by AU Heads of State and government in January 2016, the next strides involve engaging with regional economic communities (RECs), regional organisations (ROs), and member states in updating and enacting regional legal frameworks and national laws. The Model Law was endorsed by the AU as a reference guide for member states as they update or enact national laws on medical product regulation.

In order for the implementation of the AU Model Law to succeed, RECs, ROs, and member states must conduct preliminary needs assessments of the existing medicines regulatory legal framework and system in individual countries, using the Model Law as a benchmark. A roadmap must then be developed to clearly stipulate the plan of action to be undertaken based on identified gaps.

The roadmaps, together with the plans of action, constitute a comprehensive and systematic approach for responding

Implementation process of the AU Model Law



to the results of the preliminary needs assessments in individual countries and shall commence in accordance with the legislative procedures of each state.[a] RECs, ROs, and member states have a significant role to play, not only in facilitating this process, but also in owning their commitment to the implementation of the AU Model Law for harmonised medicine regulatory systems in Africa.

BENEFITS OF IMPLEMENTING THE AFRICAN UNION MODEL LAW AT THE NATIONAL LEVEL

Implementation of the AU Model Law impacts the national health regulatory systems in general and benefits can be observed at both the broader health systems level and at the technical level. The benefits of implementing the AU Model Law on the broader health systems level include:

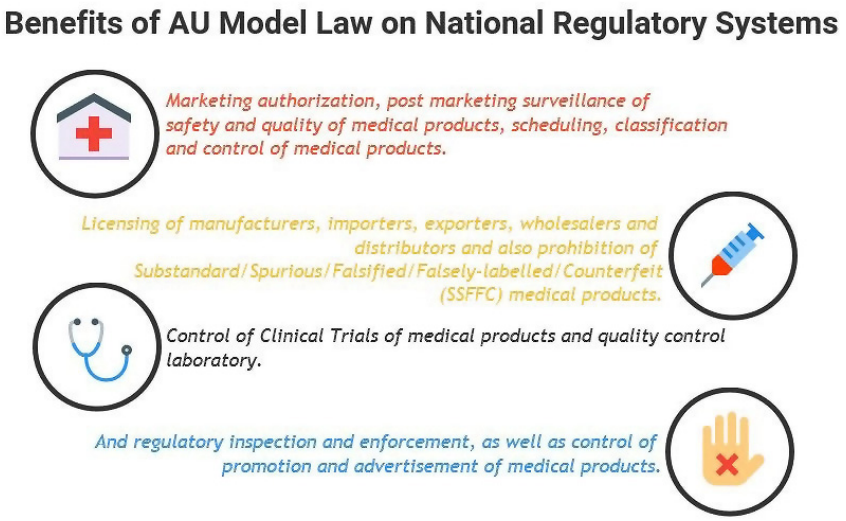
- Having national laws that meet international standards and enable the government to carry out its mandate of ensuring the right to health through the provision of high-quality, safe, and efficacious medical products to its citizens.
- Supporting universal access to health by making available the needed medical products.
- Supporting effective market control for medical products circulating in the country.
- Having legal provisions at the national level that enable regional harmonisation with other countries within the RECs and collaboration internationally.

Lessons and best practices can be drawn from countries that have already utilised the AU Model Law as a key reference document in revising their national medicines regulatory systems, such as Lesotho, Seychelles, Ivory Coast, United Republic of Tanzania (Zanzibar), and Zimbabwe. These countries serve as examples to encourage other African countries on how to utilise the AU Model Law and consequently adopt a version that responds to their needs in order to establish an effective and efficient system of medical products regulation and control and ensure that such products meet required standards of safety, efficacy, and quality. The fact that these countries have already found the AU Model Law useful paves the way to accelerate implementation in other countries. The benefits the AU Model Law brings to national regulatory systems at the technical level are enshrined in part III of the Model Law.

"EXCELLENT POLICIES, UNINTENDED FAILURES"—THE AFRICAN POLICY IMPLEMENTATION CHALLENGE

The recurrence and persistence of social, economic, and health problems on the African continent can largely be attributed to poor policy implementation strategies rather than policy formulation. Good policy frameworks exist in Africa, and policy frameworks and endorsements in the health sector usually thrive at the continental level, but challenges arise during implementation. It is at this stage that some policies, albeit well-timed and comprehensive, sometimes stagnate, leading to difficulties with actual implementation at the regional and national level.

A 2015 study involving three countries—Mozambique, Senegal, and Tanzania—published by *BioMed Central*, assessed the implementation and influence of policies that support research and innovation systems in health.[1] The findings of the study attribute the reasons for poor policy implementation in Africa to "lack of policy coherence, lack of enforcement and accountability mechanisms, and a lack of financing for



a The AU Model Law on medical products regulation full document is available at the NEPAD Agency website.

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Regional economic communities, regional organizations, and African Union member states are responsible for implementing the AU Model Law at regional and national level respectively.

implementing the policies."[1] This has led to what the World Bank labelled "excellent policies, unintended failures."[2]

The above study concludes that strong mechanisms, including financing that strengthens the position and role of government in policy coordination and oversight of the policy process, can help to increase efficient and impactful implementation of health policies. The meticulous planning behind the implementation of the AU Model Law is designed to circumvent these traditional challenges in policy implementation in Africa and has deliberately prioritised high-level consultations at the regional and national level that are flexible to respond to the specific needs of individual countries. Hence, it is important to understand how the RECs and member states approach national implementation of continental policy, as this informs the implementation of the AU Model Law.

ALIGNING POLICIES AND REGULATORY SYSTEMS AT THE NATIONAL, REGIONAL, AND CONTINENTAL LEVEL

The New Partnership for Africa's Development (NEPAD) Agency, as the technical body of the AU mandated to spearhead implementation of policy frameworks and encourage policy harmonisation, convened a Technical Working Group (TWG) on Medicines Policy and Regulatory Reforms (MPRR), which included legal experts, regulators, and strategic stakeholders and partners from RECs[b] and ROs[c] in Dakar, Senegal, to brainstorm and develop key activities to facilitate the implementation of the AU Model Law, as well as to discuss modalities for targeted national level intervention. This approach, promoted by the African Medicines Regulatory Harmonisation (AMRH), recognises the unrivalled importance of engaging

AU Model Law shall respond to preliminary national level needs assessments.

NEPAD Agency, in collaboration with the RECs, ROs, and other strategic partners, is providing technical and financial support to encourage individual member states and enable them to commission and support robust preliminary needs assessments that shall inform the implementation of a version of the AU Model Law in a manner that responds to their national needs and requirements to ensure improved medicine regulation and increased harmonization with other AU member states.

b The RECs include East African Community (EAC), Southern Africa Development Community (SADC), Economic Community Of West African States (ECOWAS) represented by the West Africa Health Organisation (WAHO), Intergovernmental Authority on Development (IGAD), West Africa Economic and Monetary Union (WAEMU), and Common Market for Eastern and Southern Africa (COMESA).

c Organisation of Coordination for the Fight Against Endemic Diseases in Central Africa (OCEAC).

RECs and ROs in advancing the medicines regulatory harmonisation agenda in their respective regions.

The approach focuses on policy alignment and regulatory reforms and aims to enhance policy coherence in RECs and AU member states for public health and pharmaceutical sector development.

The targets in the implementation of the AU Model Law at the regional and national level are that at least three regions have adopted regional policies and legal frameworks for regulation of medicines by 2020, and at least 25 countries have domesticated the Model Law on Medical Product Regulation by 2020.

The TWG on MPRR has led to the development of regional roadmaps and plans of action that aim to guide the implementation of the AU Model Law at the regional and national level. RECs and ROs are coordinating preliminary needs assessments of their member states and developing reports that identify the gaps, opportunities, and risks, as well as ways in which the AU Model Law can best be utilised to respond to these needs as well as achieve harmonisation with other countries.

The regional roadmaps and plans of action shed more light on the kind of support the TWG can render in the implementation of the AU Model Law. The East African Community (EAC) has initiated the drafting of a medicines and health technologies policy making reference to the AU Model Law recommendations as the first step to guide its partner states in the implementation and harmonisation of the AU Model Law.

WAY FORWARD ON IMPLEMENTATION OF THE AFRICAN UNION MODEL LAW

There is growing interest from AU member states, as well as countries outside the African continent, to utilise the AU Model Law. For example, the government of Tajikistan, through the World Bank, requested to have a copy of the AU Model Law in its quest to improve its national medicines regulatory environment. AU member states are therefore encouraged to utilise the AU Model Law and fulfil the commitment made by their respective governments at the continental AU level. Regional roadmaps and plans of action have been developed on the implementation of the AU Model Law with the involvement of regional bodies and member states.

In order to achieve harmonisation at the country level, national roadmaps and plans of action have to be developed by AU Member States to fit in to the regional roadmaps and plans of action. It is now imperative for respective national governments to take the following steps:

1. Commission and support in-depth needs assessments of their national medicines regulatory environments in preparation for the domestication of the AU Model Law.
2. Review regional roadmaps and plans of action in order to develop harmonised national roadmaps and plans of action for domesticating the AU Model Law.
3. Enact a version of, or parts of, the AU Model Law that strengthens their national medicines regulatory environment and drives the harmonisation agenda in Africa.

References

1 De Hhan S, Edwards D, Mugwagwa J. Assessing the implementation and influence of policies that support research and innovation systems for health: the cases of Mozambique, Senegal and Tanzania. *BioMed Central, Health Research Policy and Systems.* 2015; 13:21. Accessible at: https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-015-0010-2.

2 World Bank *South Africa Policy Brief.* World Bank; 2010. Accessible at: http://siteresources.worldbank.org/INTSOUTHAFRICA/Resources/South_Africa_policy_briefs_overview.pdf.

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