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African Medicines Regulatory Harmonisation Programme

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2016 JOINT POLICY BRIEF SERIES

Increasing access to high-quality, safe health technologies across Africa

African Union Model Law on Medical Products Regulation

Introduction

The regulation of health technologies is a critical component of every country's public health system and ensures that high-quality, safe health technologies reach the people who need them most. Unfortunately, the capacity of many low- and middle-income countries (LMICs) to evaluate and approve health technologies—and to monitor their safety, efficacy, and quality—is limited, due to inadequate resources, overburdened staff, and incoherent policy frameworks.

Additionally, regulatory legislation differs from country to country, resulting in delays for researchers and manufacturers who must navigate multiple regulatory systems to register the same health technology across countries.

Recognizing the importance of efficient and aligned regulatory systems in ensuring access to health technologies, the African Union (AU) Heads of State recently adopted the Model Law on Medical Products Regulation.

This comprehensive legislation can now be taken up by national governments and regional economic communities (RECs) to harmonise regulatory systems and increase collaboration across countries.

Ultimately, the Model Law is meant to accelerate access to lifesaving interventions, and ensure that promising health technologies are developed, tested, and scaled up to improve health impact.

Challenges in regulatory capacity and harmonisation

Access to high-quality, safe, and effective health technologies has been a challenge on the African continent for decades, due in part to weak or non-existent medicines regulatory systems. In most countries, legislation gives national governments the mandate to regulate medical products and research within their territory, through National Regulatory Authorities (NRAs). NRAs are responsible for ensuring the safety, efficacy, and quality of health technologies; they also regulate clinical trials, manufacturing, and the marketing of medical products.

The comprehensiveness of regulatory legislation—and therefore the strength of NRAs—varies from country to country, however, and many countries have not developed plans to fully implement their regulatory legislation.

Due to weak implementation of national regulatory legislation and gaps in resource allocation, many NRAs are inadequately funded, understaffed, and overburdened. As a result, NRAs often lack the expertise and experience to provide guidance to product developers who are seeking clinical trial or product registration, nor do they have proper control over numerous products that are studied, introduced, and used in their countries.

Additionally, many NRAs rely on approval from Stringent Regulatory Authorities (SRAs)—such as the European Medicines Agency, the United States Food and Drug Administration, and the World Health Organization (WHO)—as guidance for product registration, as they are well-resourced and more experienced. Yet even with the assistance of SRAs and the WHO, insufficient capacity of NRAs can lead to costly delays in product development and introduction, ultimately impacting patients in need of treatment. Because regulatory legislation—where it exists—is created at the national level, neighbouring countries can have vastly different ways of regulating and approving health technologies.

Countries are not obliged to adopt any regulatory decision made by another country, even if the evidence submitted to NRAs is identical. Researchers and manufacturers must file duplicative evidence dossiers with multiple NRAs in order to register a health technology in all countries where it could have public health impact. Each dossier submission costs time and money, and delays the availability of these technologies. Additionally, the lack of harmonisation in regulatory policy between countries hinders the opportunity for NRA collaboration and reciprocal decision-making, leading to a duplication of effort by NRA staff and regulatory backlogs.

Important regulatory stakeholders for product development in LMICs

National regulatory authorities monitor the safety, efficacy, and quality of health technologies used within a country.

The World Health Organization (WHO) provides guidance and support to countries to strengthen their regulatory capacity. The WHO prequalification (PQ) program certifies that certain health products for high-burden diseases and conditions meet stringent international standards. PQ approval is required for products to be procured by United Nations agencies.

The African Medicines Regulatory Harmonisation (AMRH) Programme was created through a joint initiative of NEPAD, PAP, and AUC—in collaboration with WHO, the World Bank, Bill & Melinda Gates Foundation, and the United Kingdom's Department For International Development —to increase access to health technologies through regulatory harmonisation and to support regional initiatives aimed at aligning medicines regulation. In the East African Community (EAC), for example, certain countries are taking the lead as technical experts on key regulatory activities so that they can provide regulatory support to other EAC countries to improve alignment with international standards.

Any medical research or clinical trial involving human subjects must be reviewed and approved by **Institutional Review Boards or Research Ethics** Committees, which ensure that research methods are ethical and that subjects are fully informed and participate voluntarily.

The Model Law: Aligning regulatory systems throughout the continent

Over the past decade, the African Union has demonstrated its support for regulatory harmonisation efforts, and some RECs have begun to streamline regulatory systems. Capitalizing on this momentum, the Pan-African Parliament (PAP), the New Partnership for African Development (NEPAD), and African Union Commission (AUC) spearheaded the development of the African Union Model Law on Medical Products Regulation. The Model Law provides a guide for AU member states and RECs in harmonising regulatory systems and providing an enabling environment for the development and scale-up of health technologies. The Model Law was developed in line with WHO recommendations and international safety and quality standards. Through the process of domestication, a country can adapt the Model Law to ensure alignment with its constitutional principles and legal system—and amend or repeal any inconsistent national laws. Once adopted and implemented by RECs and countries, the goal of the Model Law is to resolve discrepancies in current regulatory legislation and improve the efficiency and effectiveness of regulatory systems.

In accordance with the Model Law, each country must have an autonomous NRA with the power to regulate the manufacture, import, export, distribution, and use of health technologies. The NRA is also responsible for authorizing clinical trials, granting licenses to manufacturers, and setting standards for the appropriate use of new health technologies.

The Model Law also sets expectations and standards for:

•***Marketing health technologies:*** All medical products must be registered and have valid authorization to be marketed and promoted. Applications for this authorization will be reviewed by the NRA.

•***Licensing:*** Only with a license from the NRA can a person or company manufacture or distribute health technologies.

• ***Quality and safety of health technologies:*** The NRA will be responsible for monitoring and analysing adverse effects of registered health technologies and clinical trials, as well as the recall and withdrawal of substandard products. The NRA will conduct quality and safety inspections of health technologies and manufacturing facilities, and a National Quality Control Laboratory will be established for research, training, and the analysis of medical products.

• ***Clinical trials:*** In order to conduct a clinical trial with human participants, the trial must be cleared by a National Ethics Committee or Institutional Review Board and authorised by the NRA.

• ***Appeals procedures:*** The authority overseeing the NRA (e.g., the Ministry of Health) will establish an Administrative Appeals Committee to hear cases lodged against the NRA.

The Model Law also sets expectations for cooperation between NRAs at the national and regional level. All NRAs, for example, should partake in regulatory harmonisation initiatives, including the reciprocal registration of health technologies and capacity strengthening efforts. Additionally, NRAs should share intelligence on products that may pose a public health risk.

The next steps for harmonisation

The Model Law and regulatory harmonisation efforts are meant to support countries in overcoming the regulatory challenges that have long plagued the continent. Now that the AU Heads of State have adopted the Model Law, advocates have a critical role to play in ensuring that their country begins the process of domestication, ultimately enacting a version of the Model Law that fits their country's context and strengthens national regulatory capacity. By addressing gaps and inconsistencies in regulatory legislation and prioritizing harmonisation efforts, we can accelerate access to innovative, lifesaving health technologies.

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

Best practices, developing and utilizing harmonized roadmaps and plans of action

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 organizations (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.

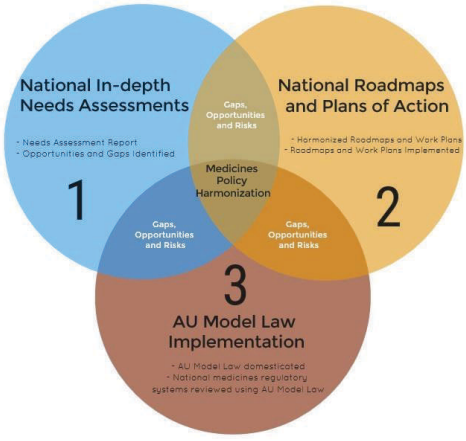


Figure 1: The above diagram summarizes the implementation process of the AU Model Law.

The roadmaps, together with the plans of action, constitute a comprehensive and systematic approach for responding to the results of the preliminary needs assessments in individual countries and shall commence in accordance with the legislative procedures of each state. 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 harmonized medicine regulatory systems in Africa.

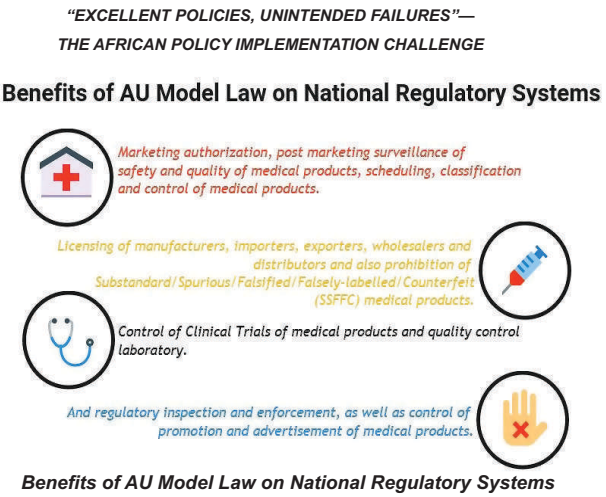
BENEFITS OF IMPLEMENTING THE AFRICAN UNION MODEL LAW AT THE NATIONAL LEVEL

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 harmonization with other countries within the RECs and collaboration internationally.

Lessons and best practices can be drawn from countries that have already utilized 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 utilize 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 is enshrined in part III of the Model Law
as represented below:



Benefits of AU Model Law on National Regulatory Systems

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, however, policy frameworks and endorsements in the health sector usually thrive at 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. The findings of the study attributes 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 implementing the policies." This has led to what the World Bank labelled "excellent policies, unintended failures."

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 prioritized high-level consultations at 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 NATIONAL, REGIONAL, AND CONTINENTAL LEVEL

The New Partnership for African Development (NEPAD) Agency, as the technical body of the AU mandated to spearhead implementation of policy frameworks and encourage policy harmonization, 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 and ROs 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 Harmonization (AMRH), recognizes the unrivalled importance of engaging RECs and ROs in advancing the medicines regulatory harmonization agenda in their respective regions.

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.

RECs, ROs, and AU member states are responsible for implementing the AU Model Law at regional and national level respectively.

The approach focuses on policy alignment and regulatory reforms which 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 utilized to respond to these needs as well as achieve harmonization 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 harmonization 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 utilize 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 their national medicines regulatory environment. AU member states are therefore encouraged to utilize 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 harmonization 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 harmonized 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 harmonization agenda in Africa.

Understanding the role of Regional Centres of Regulatory Excellence in strengthening medicines regulation in Africa

INTRODUCTION

The medical products regulation and harmonisation agenda in Africa is largely motivated by a need to increase access to essential health technologies and bolster continental innovation. An adequate health care workforce and medicines regulatory science expertise are essential factors in contributing to the realisation of this need, as well as in evaluating the efficacy, safety, quality, and performance of medical products. However, human and institutional capacity and regulatory standards and practices continue to lag behind in Africa.

In addition, an inadequate and sometimes lack of health care workforce, incoherent ad hoc training of a regulatory workforce, weak infrastructure, and unsustainable health care financing mechanisms have exacerbated the situation. As a result, many African countries still face challenges related to the delivery of quality health care.

In 2014, as a response to the noted deficits, the African Medicines Regulatory Harmonisation Programme coordinated by the New Partnership for Africa's Development (NEPAD) Agency, the technical arm of the African Union (AU), successfully led efforts to initiate the designation of Regional Centres of Regulatory Excellence (RCOREs) across the African continent.

The main aim of the designated RCOREs is to support a regulatory workforce that enhances human and institutional capacity and contributes to improved health care delivery, regulatory standards, and practices in Africa. RCOREs use multiple approaches focusing on the following important interventions:

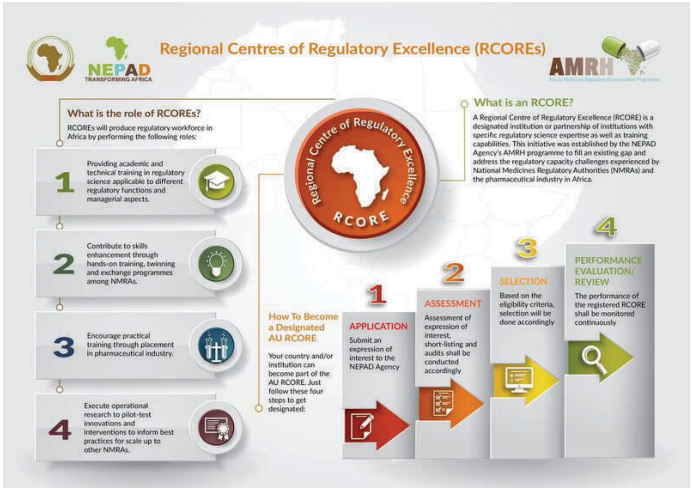
(1) Provision of academic and technical training in regulatory science applicable to different regulatory functions and managerial aspects.

(2) Skills enhancement through hands-on training, twinning, and exchange.

(3) Practical training through placement in the pharmaceutical industry.

(4) Execution of operational research to pilot-test innovations and interventions to inform best practices for scale-up to other National Medicines Regulatory Authorities.

These interventions are meant to leverage ongoing efforts to harmonise policies and regulatory frameworks in Africa and strengthen regulatory capacity. RCOREs contribute to and feed in to the



Science, Technology and Innovation Strategy for Africa (STISA) 2024 through enhancing technical and professional competence in the area of health. STISA is a key AU pillar in science, technology, innovation, and human capacity development. An outline of how an institution(s) can attain designation status

A SUMMARY OF THE EXPECTED ROLES OF RCOREs IN AFRICA

An RCORE is an institution or partnership of institutions with specific regulatory science expertise and proven capacity and capabilities in training and/or delivery of services in at least one of the categories of regulatory and managerial functions identified (see the diagram).

The 11 RCOREs were designated for a period of four years. Their performance will be evaluated, and based on the outcome of the evaluation, designation may be renewed. The NEPAD Agency will in due course publish a second Expression of Interest for designation of other interested institutions

These institutions may include, but are not limited to, those involved in medicines regulation, academia, scientific and research institutions, centres of information dissemination, and pharmacovigilance centres. There are currently eleven (11) designated RCOREs operating across the African continent in a total of eight (8) regulatory functions as represented above. Some of the activities an RCORE is expected to play include training and capacity-building in the field and category of expertise and designation, engage in information dissemination, ensure implementation of regional and national programme activities in support of medicine products regulation and harmonisation, and organise events, as well as undertake a coordination role of joint assessment and inspection activities. RCOREs have a pivotal role to play in medicines regulatory capacity development in Africa and shall contribute towards enhancing the potential of AU member states in achieving a sufficient number of qualified, experienced pharmaceutical and other professionals working in the pharmaceutical sector. An adequate and trained health care workforce will not only help increase access to essential health technologies, but also reduce the prevalence of spurious, substandard, falsely labelled, falsified, and counterfeit medical products in Africa through improving the licensing of the manufacture, import, export, distribution, promotion, and advertising of medicines according to internationally accepted standards. RCOREs also focus on building medicines regulatory science expertise in Africa, which is essential in ensuring effective medicines regulation on the continent. They are trendsetters who occupy a critical role in developing competence of experts in emerging areas of medical products regulation in Africa.

In an effort to enhance capacity and increase the regulatory workforce on the African continent, RCOREs are expected to participate in and implement the African Medicines Regulatory Professionals Fellowship Programme. The main goal of the African Medicines Regulatory Professionals Fellowship Programme is to nurture and develop technical and managerial competences to ensure effective medicines regulation in Africa.

and the private sector from within Africa and the world are at liberty to provide financial support towards the fellowship programmes in the areas of regulatory functions of RCOREs that are of interest to them or to which they wish to contribute.

The harmonisation of training manuals is a key step towards building standardised regulatory capacity in Africa. RCOREs are strategically positioned to take a lead in current efforts to develop and apply harmonised curricula in their areas of designation and specialisation. Hence, RCOREs are critical in developing, harmonising, and standardising regulatory curricula that is essential in key areas, as has been demonstrated by RCOREs in clinical trials, medicines evaluation, and pharmacovigilance. This will also contribute towards improved processes in inspection and surveillance of manufacturers, importers, wholesalers, and dispensers of medicines.

TWOFOLD APPROACH TO ACHIEVING HIGH QUALITY IN HEALTH CARE DELIVERY IN AFRICA - It is imperative to tap in to the health care workforce in Africa and the diaspora, as these have a critical role to play in the delivery of quality health care in Africa. It is particularly for this reason that the pool of regulatory experts was established by the NEPAD Agency as a resource for consultations and expert advice on health-related matters on the continent. The simultaneous approach of targeting RCOREs and the pool of regulatory experts, institutions, and individuals is a strategic one to consolidate efforts to strengthen pharmaceutical-sector development and the medical products regulation and harmonisation agenda in Africa on both fronts. AU member states are therefore encouraged to develop deliberate policies and strategies that can guarantee effective use of their nationals living in the diaspora to improve delivery of quality health care at the local level. In addition, the conditions of service for the health care workforce must be prioritised to reduce brain-drain and attract those already working in the diaspora to return back home. Mechanisms must be put in place to ensure sustained funding of both the health institutions and academic institutions (i.e., RCOREs that offer health-related training).Another critical area is that of capacity and human development.

RCOREs develop two yearly work plans and budgets in areas of regulatory capacity in the field they have been designated. While the NEPAD Agency provides advocacy and assistance in sourcing for funds to implement the work plans, AU member states and cooperating partners are called upon to be more proactive by financially supporting RCORE activities in the regulatory functions the countries have identified to be the most lacking in their respective territories. This is the only way that Africa can mitigate some of the consequences that result from an inadequate health care workforce. Countries can work closely with RCOREs to provide specialised training in areas that are weak and/or lacking. RCOREs are also essential in developing standardised regulatory training manuals of international standards. AU member states, the private sector, and organisations can tap in to this pool of knowledge to improve the technical and professional knowledge in the health care workforce through supporting research and development (R&D). This approach will not only increase the number but also enhance the quality of graduates in education for health care services in Africa. In addition, local funding for RCOREs to conduct R&D will help bring about a balance in the current status where funding for R&D is dominated by international partners in Africa. AU member states are urged to begin by mobilising local resources to support RCOREs and make sure that these are used prudently and engage international partners where necessary. Above all, the onus is on the AU member states to provide support towards sponsoring the African Medicines Regulatory Professionals Fellowship Programme under RCOREs and ensuring its sustainability. This will contribute towards building ownership in the health workforce, and the AU member states will be able to channel education resources to specific medicines regulatory challenges that are most profound and lacking in the continent. AU member states can set their own conditions and improve not only the academic excellence in the health care workforce, but also target individuals already in practice for training and retraining to boost their knowledge. RCOREs make it possible to strengthen and develop collaboration on health care education development in Africa based on South-South collaboration and common experiences.

RCOREs have therefore been established to support AU member states in improving healthcare delivery and training of the health workforce. The success and sustainability of RCOREs rely on the support of the AU member states and collaborating partners.

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