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.

PATH/Felix Masi

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.

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.

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.

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 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.

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