

# Medicines Regulation in the East African Community

## Landscape summary report

### INTRODUCTION

The regulation of health technologies is a critical component of every country's public health system and ensures that high-quality vaccines, devices, diagnostics, and drugs reach the people who need them most. Medicines regulation, however, differs from country to country, which can result 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 facilitating access to health technologies, many countries are working across regional economic communities (RECs) to harmonize regulation. These harmonization efforts increase collaboration across countries, strengthen regulatory capacity of partner states, and ensure the efficient evaluation of high-quality, safe health technologies.

The East African Community (EAC) has demonstrated commitment to streamline medicines regulation and build regulatory capacity across partner states; it is one of the first RECs in Africa to develop and implement harmonization programs. Through the EAC Medicines Regulatory Harmonization (EAC MRH) initiative and other regional strategies, the EAC aims to decrease the amount of time taken to register essential medicines to treat priority diseases and reduce duplication of efforts through mutual recognition of decisions made by partner states' national regulatory authorities (NRAs).

Despite this regional progress, challenges in achieving regulatory harmonization remain. The EAC Secretariat and partner states have limited infrastructure and human resources to regulate all types of health technologies, and regulatory capacity varies widely from country to country. The implementation of harmonization efforts has also been slow, and funding is limited and largely donor dependent. While there is support for harmonization from donors, there is limited awareness among key stakeholders within partner states about ongoing harmonization activities. These challenges weaken EAC harmonization efforts and must be addressed to ensure that promising health technologies are developed, tested, and scaled up to improve health impact.

### LANDSCAPE OF THE EAC'S REGULATORY ENVIRONMENT FOR HEALTH TECHNOLOGIES

To better understand the status of regional harmonization efforts and opportunities for advocacy, PATH commissioned the East African Health Platform (EAHP) to conduct a landscape of policies, regulatory stakeholders, and harmonization activities taking place at the EAC level and within partner states. A literature review and consultations with regulatory experts, government officials, and researchers identified regulatory harmonization initiatives, as well as challenges to their implementation. This document provides an overview of current regulatory systems at the EAC level and within partner states. It also summarizes key challenges and other findings and identifies potential solutions that could be the focus of future policy advocacy efforts.

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 may also regulate clinical trials, manufacturing, and marketing of medical products. The comprehensiveness of regulatory legislation—and therefore the strength of NRAs—varies from country to country.

### OVERVIEW OF THE EAST AFRICAN COMMUNITY

The EAC is an economic community that includes six partner states—Burundi, Kenya, Rwanda, Tanzania, Uganda, and most recently, South Sudan.<sup>a</sup> Established in 2000, the aim of the EAC is to strengthen political, economic, social, and cultural cooperation among partner states and to improve trade and investment in the region. The EAC Secretariat, based in Arusha, Tanzania, is the executive body of the EAC and is headed by the Secretary General (Table 1).

<sup>a</sup> South Sudan was admitted to the EAC in March 2016, after the EAHP conducted its landscape and stakeholder interviews. Information about South Sudan's medicines regulation is therefore not included in this report.

**TABLE 1. EAC governance structure.**

Summit of the Heads of State	Comprised of each country's head of state, the summit is the driving force for the development and achievement of EAC objectives. The summit also approves proposed EAC bills.
Council of Ministers	As the policy-making body of the EAC, the council consists of ministers from each partner state responsible for regional cooperation. The council promotes and monitors the implementation of EAC programmes.
Coordination Committee	The Coordination Committee consists of the permanent secretaries responsible for regional cooperation from each partner state. It reports to the Council of Ministers and is responsible for implementing decisions of the summit and council, as well as the coordination of Sectoral Committee activities.
Sectoral Committees	Sectoral Committees are composed of senior officials from sector ministries (e.g., trade, finance, health, agriculture, and environment) in partner states. Committees are responsible for priority setting at the EAC level and preparing comprehensive implementation programs for their sector.
Secretariat	The Secretariat is the executive body of the EAC and is headed by the Secretary General, who is appointed by the summit. The Secretary General is the executive and accounting officer of the EAC and the secretary of the summit.

Decision-making within the EAC is based on consensus from all partner states. Per the EAC treaty, partner states are compelled to implement EAC regulations, directives, and decisions. But because the treaty is non-self-executing, policies approved at the EAC level require a change in domestic legislation by national parliaments. For example, not all partner states have complied with the 2000 Council of Ministers Resolution requiring the establishment of autonomous NRAs to control medicines and food products. Though states are part of the decision-making process at the regional level, national parliaments ultimately have the power and responsibility to align domestic and EAC policies (Figure 1).

#### **EAC MEDICINES REGULATORY HARMONIZATION INITIATIVE**

In 2012, the EAC launched the EAC Medicines Regulatory Harmonization (EAC MRH) initiative, which helps partner states build and strengthen medicines regulatory systems through regional coordination and policy alignment. Because the NRAs of member states—where they exist—vary widely in their regulatory ability, capacity strengthening of NRAs is also a primary objective of the EAC MRH initiative. Through joint assessment and approval of applications for medicines registration, harmonization aims to decrease registration time, reduce duplicative efforts of NRAs, and streamline the use of resources.

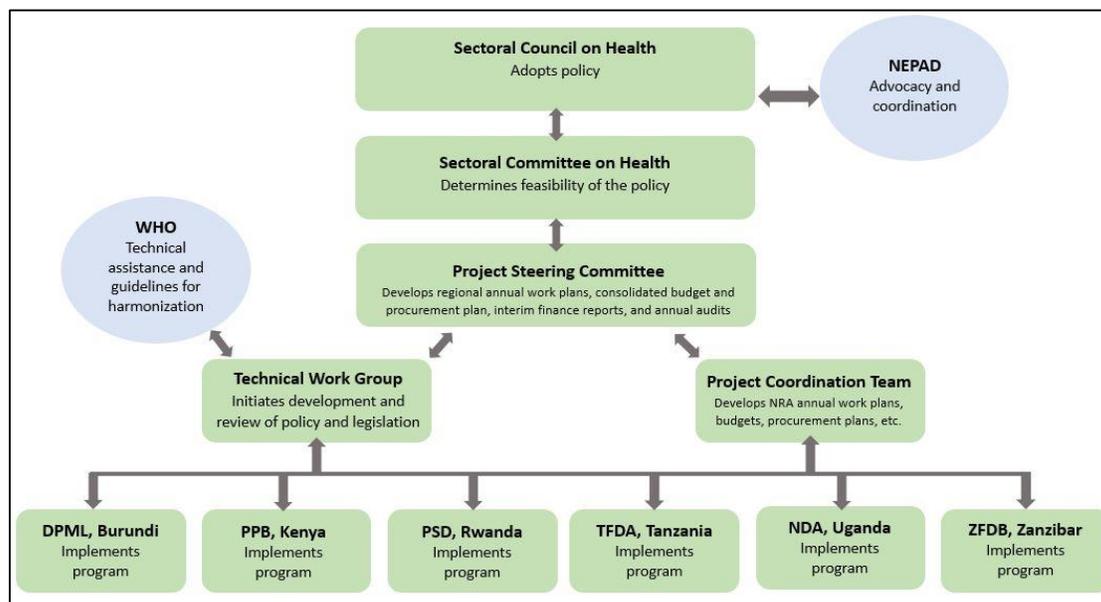
In implementing the EAC MRH initiative, member states lead technical working groups on key regulatory activities, including:

- Good Manufacturing Practice (GMP), led by Uganda
- Information Management Systems (IMS), led by Rwanda
- Medicines Evaluation and Registration (MER), led by Tanzania
- Quality Management Systems (QMS), led by Kenya

These working groups have developed harmonized guidelines, requirements, and standards for GMP, MER, and QMS, which were approved by the Council of Ministers in September 2014. Guidelines for the development of a common IMS for medicines registration is in draft form. Technical working groups also provide regulatory support to EAC member states to improve alignment with international standards.

In addition to developing common technical documents, the EAC Secretariat and member state NRAs—in collaboration with the World Health Organization (WHO) and Swiss Agency for Therapeutic Products—began joint dossier assessment in 2015. So far, eight applications for medical product registration have been evaluated by partner states. WHO has also worked with technical experts in the EAC to jointly inspect facilities in Kenya and Uganda for GMP compliance.

FIGURE 1. EAC decision-making structure



#### EAST AFRICAN HEALTH RESEARCH COMMISSION

To support joint health research, the EAC developed the Protocol on the Establishment of the East African Health Research Commission (EAHRC), which created a regional body responsible for the coordination of health-related research. The EAHRC promotes collaborative research and development (R&D) programs; provides standardized research protocols, guidelines, and proposals; strengthens research capacity; and establishes quality assurance measures for health R&D. To increase cooperation across partner states, the EAHRC is also responsible for establishing and maintaining national and regional databases on health research capacity and activities in the region. Finally, the EAHRC facilitates the development of evidence-based, regional health policies and implementation within partner states.

#### EAC REGIONAL PHARMACEUTICAL MANUFACTURING PLAN OF ACTION, 2012–2016

Approved by the Sectoral Council of Ministers of Health in 2011, the EAC Regional Pharmaceutical Manufacturing Plan of Action (EACRPMPoA) defines the EAC’s strategy for strengthening local pharmaceutical manufacturing. Access to high-quality, affordable health technologies remains a challenge in the EAC, due in part to inadequate local production and a reliance on imported medicines. To address this challenge, the plan’s main objective is to improve the national and regional capacity to sustainably and competitively produce quality-assured essential medicines for local use and export—which will lead to economic growth. The plan calls for increased investment in pharmaceutical production, improved capacity of regional

#### Global and African Union initiatives impacting regulatory systems for health

- 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 New Partnership for Africa’s Development (NEPAD), Pan African Parliament (PA), and African Union Commission (AUC)—in collaboration with WHO, the World Bank, the 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.
- **The Pharmaceutical Manufacturing Plan for Africa (PMPA)**, endorsed by the African Union in 2007, aims to strengthen pharmaceutical manufacturers on the continent to produce high-quality, affordable medicines. A robust local pharmaceutical sector will increase access to essential medicines, ensure a sustainable supply, and lead to improved public health outcomes, as well as industrial and economic development.

manufacturers, and strengthened regulatory systems through capacity strengthening and regional harmonization.

The EAC Secretariat established a regional working group, composed of stakeholders from the health sector and industry, to address the development of the pharmaceutical industry. The Federation of East African Pharmaceutical Manufacturers has also been engaged and is advocating for tax incentives and preferential pricing to bolster member competitiveness.



PATH/Lesley Reed

## REGULATORY FRAMEWORK IN EAC MEMBER STATES

Despite a 2000 Council of Ministers Resolution requiring the establishment of autonomous NRAs in each country, just three EAC member states—Kenya, Tanzania, and Uganda—have operational and autonomous NRAs. Burundi and Rwanda carry out medicines regulatory functions within their national ministries of health (MOH), but both are currently in the process of establishing NRAs, though timelines remain unclear. The following profiles outline the regulatory body of each member state, provide information on engagement in harmonization efforts, and reveal challenges in achieving regulatory alignment.

### Burundi

Burundi's Ministry of Public Health and the Fight against AIDS develops health-related policy and oversees the Directorate of Pharmacy, Medicines, and Laboratories (DPML), which functions as the country's medicines regulatory authority. The DPML only regulates medicines—not vaccines, medical devices, or diagnostics—and does not have the capacity to provide oversight for clinical trials. This gap in regulation is largely due to chronic shortages of human, technical, and financial resources; a lack of infrastructure; and an inadequate legal regulatory framework. Moreover, the DPML relies on the budget allocated to the Ministry of Public Health, which continues

to decline, leaving the DPML unable to allocate resources to the EAC MRH initiative.

Burundi has fast-tracked the enactment of a legal framework to recognize regulatory decisions made by NRAs of other partner states—but stakeholder interviews revealed that this does not yet happen in practice. Additionally, the Ministry of Public Health has not enacted a national health research policy, and coordination between entities involved in health research is lacking.

The DPML has, however, engaged in the EAC MRH initiative through participation in technical working groups to develop regional documents. The government also plans to enact legislation that would establish a semi-autonomous NRA to regulate medicines, devices, diagnostics, and clinical trials.

### Kenya

The government of Kenya has created a complex policy framework for medicines regulation. The Pharmacy and Poisons Board (PPB) is Kenya's medicines regulatory authority and is responsible for the regulation of pharmaceutical products, registration of medicines, and some aspects of clinical trial approval. Medical device regulation, however, is divided between PPB, the Kenya Bureau of Standards, and the Kenya Radiation Board. The National Commission for Science, Technology, and Innovation (NACOSTI)—in its mandate to regulate and assure quality in the science, technology, and innovation sector—provides regulatory oversight.

The number of government entities involved in regulation contributes to a long and complex regulatory pathway that research institutions, the private sector, and other innovators must navigate in order to register a health product or receive clinical trial clearance. Preclinical trials, for example, require research permits from six different regulatory agencies. A draft piece of legislation, however, aims to harmonize national policies related to food and drug regulation and create an independent national authority, known as the Kenya Food and Drugs Authority (KFDA), with a broader mandate than the PPB. A task force composed of government bodies and technical experts are currently developing the KFDA bill.

In addition to efforts to streamline the medicines regulatory framework, the PPB leads the EAC MRH initiative's technical working group on QMS, which developed a compendium to enable partner states to adopt standard quality systems requirements.

Despite this progress, an interviewee pointed to concerns about varying regulatory capacity and resources across countries—and the potential for these disparities to delay harmonization. The need for regional legislation to be domesticated and adopted by each country is also likely to lead to delays. Other stakeholders were wary of harmonization because of potential revenue loss for member states in the form of application and registration fees. Finally, interviews revealed that knowledge of the EAC MRH initiative varies widely—many stakeholders in the pharmaceutical industry, for example, have not been involved in regulatory harmonization discussions.

### Rwanda

The Pharmaceutical Service Directorate (PSD), a division of Rwanda’s Ministry of Health, is responsible for medicine registration, oversight of medicines procurement and production, policy development, and pharmacovigilance. Diagnostics, vaccines, and medical devices, however, are not currently regulated. Though the PSD is also mandated to align the country’s regulatory system with the EAC MRH initiative, Rwanda’s relatively weak regulatory policy environment has resulted in slow progress in developing policies to facilitate regional harmonization. In 2013, the government of Rwanda passed a law that establishes the Rwanda Food and Medicines Authority and outlines its function—to regulate pharmaceutical products, medical devices, and other health commodities. It is unclear, however, to what extent this law has been implemented.

In Rwanda, the EAC MRH initiative is generally viewed as a positive step toward increasing access to high-quality, affordable medicines. The PSD has actively engaged in harmonization through its leadership of the IMS technical working group. Despite the initiative’s capacity-strengthening efforts, however, Rwanda continues to have significant gaps in human resources—both in numbers and technical skills. Additionally, there has been little technical or financial support from the Rwandan government toward the EAC MRH initiative, and outside of the MOH, many interviewees had little knowledge about the harmonization process.

### Tanzania

The mandate of Tanzania’s medicines regulatory body, the Tanzanian Food and Drug Authority (TFDA), includes product evaluation and registration to ensure the quality, safety, and efficacy of drugs and medical devices. The TFDA also regulates clinical trials, manufacturing, and distribution of health technologies, and the Directorate of Inspection and Surveillance within the TFDA inspects manufacturers, wholesalers, retailers, and clinical trial sites.



PATH/Doune Porter

Traditionally, the local manufacturing sector in Tanzania has been strong—local production supplied about one-third of the country’s medicines in 2009, and manufacturers developed a successful distribution system to supply medicines to many rural districts. This industry has recently been compromised, however, by less expensive imports, required technology upgrades, human resource constraints, and weak links with international pharmaceutical industries to foster technology transfer. To address these challenges, the government is developing incentives for local manufacturers, such as import restrictions on locally available, high-quality products and tax breaks.

Stakeholder interviews revealed that local manufacturers feel they have not been adequately engaged in the EAC MRH initiative and are not included in the regional steering committee on harmonization. Manufacturers fear that they cannot meet the high standards proposed by the initiative. Though the TFDA has assessed joint dossiers for medical product registration under the EAC MRH initiative, all applications came from foreign manufacturers. To level the playing field, some stakeholders proposed a GMP Road Map for Tanzania—similar to Kenya’s—to provide a phased approach for increasing manufacturing capacity.

Beyond dossier assessment, the TFDA has engaged with the EAC MRH initiative in various ways. The TFDA leads the technical working group on MER, which developed a compendium that outlines harmonized medicines registration procedures. This document aids partner states’ NRAs in managing applications for medicines registration and provides manufacturers with guidelines to follow when preparing a product dossier. There is no clear information, however, about what resources the TFDA invests in the EAC MRH initiative.

### Uganda

The government of Uganda developed a policy framework for medicines regulation and health R&D through the

National Drug Policy (2002). The National Drug Authority (NDA) is mandated to ensure the quality, safety, and efficacy of medical products and regulate their production, importation, distribution, and use. The NDA also oversees manufacturing and licensing. Medical devices and diagnostics, however, are not regulated by the NDA, according to EAC staff who were interviewed.

Uganda also has two research bodies; the Uganda National Council of Science and Technology (UNCST) oversees and coordinates research across sectors, whereas the Uganda National Health Research Organization (UNHRO) focuses on health research specifically. Research involving animal and human health products must be approved by the NDA and UNCST.

The NDA is responsible for implementing EAC MRH activities, in collaboration with UNCST and UNHRO. Uganda leads the technical working group on GMP, which developed a compendium of technical documents to guide NRAs in managing inspections of manufacturing facilities. Apart from this work, however, respondents revealed that all harmonization activities are being coordinated at the regional level by EAC staff—there has been very little involvement of national-level technical experts, citizens, and other stakeholders. This has led to concerns about how the harmonized documents will be implemented if those who use them are not consulted in the development process. More broadly, there is no clear mechanism or plan for how harmonized documents will be implemented at the national level.

Uganda has not provided funding specifically for the EAC MRH initiative, according to interviewees, which raised questions about harmonization’s sustainability—most funding has come from external sources. Moreover, because the NDA depends on medicines registration fees, some respondents were concerned about losing this source of funding.



PATH/Will Boase

## CHALLENGES IN ACHIEVING HARMONIZATION

Though the EAC has demonstrated commitment to streamlining medicines regulation and strengthening regulatory capacity across partner states, stakeholders interviewed by EAHP identified a number of barriers to full implementation of harmonization initiatives. The following challenges must be addressed to ensure that promising health technologies are developed, tested, and scaled up to improve health impact.

### Limited and varied capacity

The EAC Secretariat and many partner states have limited infrastructure and human resources to regulate health technologies, and regulatory authority capacity varies widely from country to country. These asymmetries in capacity and resources have made harmonization difficult; whereas Kenya, Uganda, and Tanzania have operational and autonomous regulatory authorities, Burundi and Rwanda carry out medicines regulatory functions through their national MOHs. Moreover, some national regulatory bodies regulate clinical trials, medical devices, and diagnostics, whereas others lack the capacity or mandate to do so. Variances in skill, capacity, and resources complicate mutual recognition of regulatory decisions and joint registration.

Ensuring a constant supply of essential medicines is also difficult due to inadequate local production of pharmaceuticals. Although countries like Kenya and Tanzania have a stronger manufacturing sector, it is often difficult for new manufacturers to be competitive, at least initially, without incentives or preferential procurement. Moreover, existing manufacturers are concerned about GMP requirements proposed by the EAC MRH initiative and whether they will have the capital to make required improvements up-front. Though the EACRPMPoA envisions harmonization as necessary in facilitating local pharmaceutical production, there is concern among stakeholders that EAC MRH requirements might slow manufacturing growth. Additionally, there is an insufficient number of quality control laboratories for medicines in the EAC—only one laboratory in Kenya is prequalified by WHO.

### Delayed implementation

Many respondents stated that the implementation of harmonization efforts has progressed slowly and is exacerbated by the need to establish NRAs in some partner states and strengthen weak authorities in others. Though the EAC treaty compels partner states to implement EAC regulations, directives, and decisions, the treaty is non-self-

executing. Therefore, policies created at the EAC level require a change in the domestic legislation of all partner states—national parliaments have the ultimate decision-making authority.

Respondents also pointed to the absence of a clear strategy for how different NRAs will work together. EAC legislation on medicines registration is very broad, and though it states that countries will harmonize medicines regulation, there is little detail about the required changes to domestic legislation or the timeline.

Implementation of the EAHRC has also been slower than anticipated. The Protocol on the Establishment of the EAHRC was passed in 2008, but the EAC Secretariat has allocated limited financial and human resources to the EAHRC. Its capacity and resources need to be strengthened before it can fulfill its mandate of coordinating health-related research in the region.

#### Donor-dependent funding

Though the EAC has a strong interest in regulatory harmonization, governments have not committed significant financial resources to harmonization efforts. Instead, the EAC MRH initiative is largely funded by donors, such as WHO, World Bank, and the Gates Foundation. These donors have been instrumental in initiating harmonization efforts, but a lack of partner state investment poses long-term challenges for sustainability.

#### Limited awareness among key stakeholders

While there is extensive support for harmonization from donors, there is limited awareness among key stakeholders within partner states, including civil society, the private

sector, and technical experts. Many respondents viewed harmonization as a top-down initiative, driven by external parties who may not adequately understand roadblocks to implementation. There was also a desire for increased consultation of regulatory staff who will be using common technical documents created by the EAC Secretariat and technical working groups.

#### **THE PATH FORWARD**

Despite these challenges, the EAC and member states can create a more enabling environment for medicines regulatory harmonization. Potential solutions include the development of a regional policy framework for harmonization, continued capacity-strengthening efforts for national regulatory bodies, support for the local manufacturing industry, increased domestic resources, and the expansion of the EAC MRH initiative to include clinical trial oversight and medical device and diagnostic regulation. Additionally, increased stakeholder engagement—including civil society, local manufacturers, and technical experts—would bolster support for the harmonization process. By prioritizing harmonization efforts and strengthening regulatory capacity across NRAs, partner states can significantly improve the timely registration of essential medicines and reduce duplication of efforts through mutual recognition of regulatory decisions.

Moving forward, advocates have a critical role to play in ensuring that the EAC MRH initiative and other regional strategies are translated into domestic policy—and that partner states address gaps and inconsistencies in regulatory legislation. Through efficient and aligned medicines regulatory systems, the EAC can accelerate access to innovative, lifesaving health technologies.



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455 Massachusetts Ave NW  
Suite 1000  
Washington, DC 20001 USA