POLICY BRIEF

Navigating the Research Approval and Regulatory Landscape for Health Technologies in Kenya

The processes by which countries regulate health technologies and approve health research can have a profound impact on whether high-quality vaccines, devices, diagnostics, and drugs are accessible to those who need them most. To bolster innovation and improve health outcomes for their citizens, governments must be able to efficiently coordinate, oversee, and carry out medicines regulatory functions.

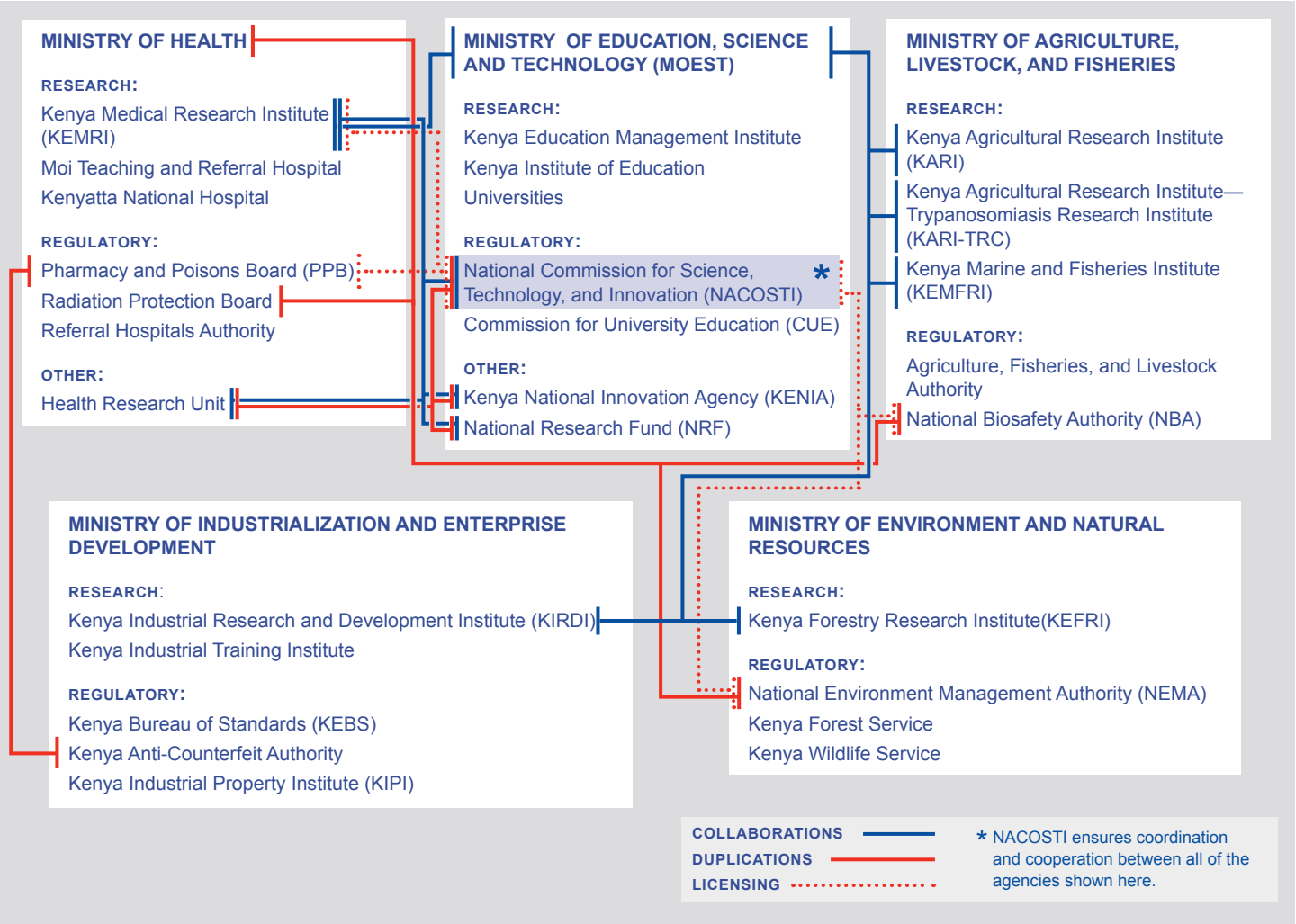
The government of Kenya has demonstrated commitment to strengthening its regulatory environment and supporting the efficient evaluation of health technologies and clinical research. The government has developed a robust regulatory framework, which includes a number of regulatory agencies and research institutions, each overseen by various government ministries. Yet despite this progress, there are many bottlenecks in the regulation of health technologies and research clearance, as well as a duplication of roles in the government bodies involved. Regulatory agencies and research organizations are spread across ministries and are often governed by conflicting legislation. Their overlapping mandates can lead to confusion for researchers and innovators attempting to navigate the system, and coordination mechanisms between government bodies involved in licensing are limited.

To better understand these challenges and opportunities for advocacy, PATH commissioned the Scinnovent Centre to conduct a landscape of the health research and regulatory approval processes in Kenya and potential causes of delays. Through document reviews and key informant interviews, challenges related to medicines regulation and research clearance emerged. This document provides an overview of the regulatory landscape, summarizes challenges and other findings, and offers recommendations for strengthening regulation and research approval in Kenya. Ultimately, this analysis aims to provide researchers and advocates with a framework for engaging with key regulatory stakeholders and advocating for strengthened regulatory policies.

THE REGULATORY LANDSCAPE IN KENYA

Responsibility for the regulation of health technologies and approval of research is spread across multiple government ministries, regulatory bodies, and research institutions, each of which bring diverse expertise and value to the process (see Figure 1). The number of government entities involved, however, 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 research approval. Additionally, there is often overlap in the policies and guidelines that govern the regulatory system. Various government bodies involved in regulation and research

Figure 1. Related Research and Development Entities in Kenya



approval derive their mandates from different policies, which has often led to duplicative, unclear roles and responsibilities. Key players and policies governing the regulatory landscape are outlined below.

REGULATING RESEARCH IN KENYA

The approval of research is critical to ensuring that all proposals uphold ethical standards and are aimed at improving human well-being. The approval process is also a mechanism for coordinating research between various public research institutions, limiting duplication of efforts, and disseminating resulting knowledge. In Kenya, the Ministry of Education, Science, and Technology (MOEST) is a key player in regulation and research approval and is responsible for all policy development and implementation related to science, technology, and innovation (ST&I). In terms of research coordination, MOEST provides oversight and quality assurance for six public research institutes, which are all domiciled in different ministries (see Table 1).

MOEST also oversees the National Commission for Science Technology and Innovation (NACOSTI), a regulatory body that is mandated to assure quality in the ST&I sector, set national ST&I priorities, coordinate research activities, and advise the government on related policy. All scientific research—health-related or otherwise—must be approved by NACOSTI. Due to increasing research activity in Kenya, NACOSTI established the National Bioethics Committee (NBC) to promote and monitor ethical practices and accredit institutional ethics review committees (IERCs). IERCs then conduct ethical reviews of research protocols on behalf on NACOSTI. The Kenya Medical Research Institute (KEMRI), for example, has been accredited by NACOSTI to conduct ethical reviews and approve biomedical research.

Research permits are mandatory for all individuals and institutions conducting research in Kenya, save employees of government research institutions. Applicants must submit an online application to NACOSTI, which processes applications and sends them to relevant experts for assessment. In addition to NACOSTI, however, researchers may have to secure permits or letters of authorization from many other regulatory bodies. For example, health-related research requires ethical clearance from an accredited IERC, while access to genetic or biological materials requires

an access permit from the National Environment Management Authority. To conduct a pre-clinical trial, a researcher must obtain permits from six different regulatory agencies. These requirements can significantly slow the research process and may dissuade critical research from being carried out in Kenya.

REGULATING HEALTH PRODUCTS IN KENYA

Central to the regulation of health technologies in Kenya is the Pharmacy and Poisons Board (PPB), housed within the Ministry of Health. As the national medicines regulatory authority, the PPB is responsible for the regulation of medicines and medical devices, registration of pharmaceutical products, and some aspects of clinical trial approval. The PPB also regulates the manufacturing of health products to ensure quality control and compliance with good manufacturing practice (GMP). The National Quality Control Lab (NQCL) was established as the technical arm of the PPB to examine and test drugs—both locally manufactured and imported—to ensure their quality.

Though the PPB is the primary regulator of health technologies, there are numerous regulatory bodies within other ministries that may be involved. This creates a complicated pathway for health technology approval and registration, which can discourage innovation. Many policies and guidelines governing the regulatory system have conflicting information or provide overlapping mandates for regulatory bodies. For instance, the Pharmacy and Poisons Act and the Food, Drugs, and Chemical Substances Act both include provisions on the manufacture, sale, and advertisement of drugs and medical devices, and licensing power is delegated to different government authorities. As a result, researchers and innovators must seek approval from multiple government bodies and pay separate fees for registration.

Additionally, manufacturers, wholesalers, and distributors of health technologies must obtain multiple licenses and permits from different agencies, which can be time consuming and costly. For example, in addition to fees paid to the PPB for registration, GMP inspection, and manufacturing licenses, local manufacturers must also pay a levy to the Kenya Bureau of Standards, a regulatory agency housed in the Ministry of Industrialization and Enterprise Development. This duplication contributes to lengthy and expensive registration processes and can be a disincentive for local manufacturers and industry stakeholders—ultimately delaying patients' access to lifesaving medicines.

POST-MARKETING SURVEILLANCE IN KENYA

After health technologies are approved for use, the PPB is responsible for post-marketing surveillance—the monitoring of health technologies to ensure their quality, safety, and efficacy—also called pharmacovigilance. In 2009, the PPB established the National Pharmacovigilance Centre. Since then, more than 10,000 people from the public and private sectors, such as health-care workers and pharmacy students, have been trained in pharmacovigilance. The PPB has also developed tools for pharmacovigilance, including an online reporting system that allows health care workers and consumers to report poor quality medicines or any suspected adverse drug reactions. In 2014, the PPB

Table 1. Public research institutes overseen by MOEST:

	Kenya Medical Research Institute (KEMRI) is situated in the Ministry of Health (MOH) and is responsible for biomedical research. NACOSTI has accredited KEMRI to conduct ethical reviews and approve biomedical research.
	Kenya Industrial Research and Development Institute's (KIRDI) mandate includes industrial research, including civil, mechanical, electrical, and chemical engineering and food technology. It sits within the Ministry of Industrialization and Enterprise Development.
	Kenya Agricultural Research Institute (KARI) oversees research in agriculture and veterinary sciences and is housed in the Ministry of Agriculture, Livestock, and Fisheries.
	Kenya Agricultural Research Institute—Trypanosomiasis Research Institute (KARI-TRC) conducts research on human and animal trypanosomiasis and is domiciled in the Ministry of Agriculture, Livestock, and Fisheries (its functions were previously situated within the MOH).
	Kenya Marine and Fisheries Institute (KEMFRI) is domiciled in the Ministry of Agriculture, Livestock, and Fisheries and conducts research in marine and freshwater fisheries and aquatic biology.
	Kenya Forestry Research Institute (KEFRI) is responsible for forestry research and sits within the Ministry of Environmental and Natural Resources.

was chosen to host the regional center of excellence for pharmacovigilance in Africa.

Though Kenya's post-marketing surveillance system is a model for the region, the legal framework has proven difficult to navigate at times. There are three laws in Kenya that include anti-counterfeit measures to set standards, curb illicit trade, and create institutions for enforcement—the Anti-Counterfeit Act; the Food, Drugs, and Chemical Substances Act; and the Industrial Property Act. In some situations, it is unclear which law is applicable or what agency has jurisdiction in setting punishments for counterfeiting or determining when intellectual property infringement has occurred. The High Court has sought to clarify overlapping roles in the past—in 2002, the Anti-Counterfeit Act was ruled partly unconstitutional, as it infringed on citizens' right to access health care through more affordable generic products. Kenyan lawmakers have not, however, reviewed the act, so enforcement continues to be a challenge.

RECOMMENDATIONS

Despite the challenges faced by Kenya's regulatory system, potential policy solutions exist for creating a more enabling environment for the efficient approval of health technologies and clinical research. Recommendations include:

Enhancing policy coherence: Through policy alignment and clarification, government bodies involved in the regulation of health technologies and research clearance should have clear, complementary mandates. Research approval processes should be streamlined, and regulatory harmonization at the East African Community level should be prioritized as a method of sharing best practices and fast-tracking registration of medicines for priority diseases. At the national level, a draft piece of legislation that would harmonize national policies related to food and drug regulation is already being considered by the government. This bill would create an independent national authority, known as the Kenya Food and Drugs Authority (KFDA), with a broader mandate than the PPB. As the lead regulator of health technologies, the KFDA would address many challenges in overlapping policies and roles of various government entities.

Reducing burdensome licensing requirements: The multiple laws and agencies involved in licensing health technologies should be reviewed and simplified to lessen the time-consuming and costly burden on manufacturers, wholesalers, and distributors. By streamlining the number of licenses and permits needed, Kenya can more strongly encourage innovation and local industry. To this end, the establishment of the KFDA would help lessen the number of licenses and permit fees currently required through the alignment of national policies and regulatory bodies.

Strengthening pharmacovigilance: In addition to clarifying overlaps in the legal framework for pharmacovigilance, it is critical for Kenya to take further action against the importation of substandard and counterfeit medicines. Industry stakeholders have suggested that certification from an agency that meets internationally recognized standards for good laboratory practice be required for an import permit. Other suggestions include the testing of health technologies upon arrival in Kenya or random testing of drug samples before entering the supply chain to monitor quality.

Streamlining stakeholder coordination: To better support cross-ministry coordination, agencies with regulatory functions that span across several ministries (e.g., NACOSTI) should be housed in a government body with appropriate convening power, such as the Office of the President or Prime Minister. Additionally, there should be an inter-agency or inter-ministerial mechanism to bring all relevant stakeholders together to discuss issues affecting the sector. NACOSTI, or another agency with a cross-cutting mandate, could provide this platform.

THE PATH FORWARD

Recognizing the potential of policy advocacy to impact Kenya's regulatory system, a group of nongovernmental organizations has launched the Coalition for Health Research and Development (CHReaD). This coalition of advocates and technical experts from across the health spectrum advocates for increased investment, improved policies, and streamlined regulatory processes that support the development, introduction, and scale up of high-impact health technologies. By creating an enabling policy environment for health research and development, Kenya can encourage innovation and pursue solutions that reflect its greatest health needs. **Please contact Hesbon Simba (hsimba@path.org), research and development advocacy officer at PATH, for more information about how to become involved.**