

Research and Development for Health in Kenya

Landscape analysis executive summary

INTRODUCTION

The investment in research and development (R&D) by low- and middle-income countries is critical to ensuring that high-impact, affordable health technologies reach the people who need them most. In addition to enhanced economic growth and better social outcomes, domestic investment in R&D guarantees that solutions reflect a country's most urgent health needs.

The government of Kenya has demonstrated a commitment to health R&D, passing a number of policies and strategies in recent years aimed at bolstering the country's innovation agenda. Accompanying these policies are multiple commitments—both regional and international—to increase funding for R&D activities. A rapidly growing gross domestic product (GDP) affords Kenya the opportunity to further support its growing health R&D sector and research infrastructure.

Despite Kenya's relatively supportive policy environment for health R&D, many challenges remain. The implementation of important health R&D-related policies has been slow, and actual funding remains a fraction of commitments made by the government. Additionally, the many government entities that oversee, regulate, and carry out health R&D activities have duplicative and unclear roles and responsibilities, making it difficult for researchers and innovators to navigate approval processes. These barriers contribute to a weak innovation system in Kenya, which must be stimulated in order to translate science, research, and technology development into economic growth and a higher quality of life for its people.

LANDSCAPE OF KENYA'S R&D AND REGULATORY ENVIRONMENT FOR HEALTH

To better understand these challenges and identify potential solutions, PATH commissioned the Council on Health Research for Development (COHRED) to conduct a landscape analysis of policies, advocacy initiatives, stakeholders, and funding trends related to health R&D and regulatory processes. Through a literature review and consultations with more than 40 R&D policy experts and stakeholders, five overarching challenges impeding health R&D progress in Kenya emerged. This document

summarizes these key challenges and other findings, and identifies potential solutions that could be the focus of future policy advocacy efforts.

Strengthening governance structures and coordination

The government of Kenya has created a robust policy framework for managing, coordinating, and funding R&D (Table 1). Yet stakeholders noted that implementation of these policies and strategies has been slow and often characterized by disjointed and duplicative efforts by various government actors. The 2013 Science Technology and Innovation (ST&I) Act sought to increase coordination in the ST&I sector by establishing three government bodies with complementary mandates:

- **National Commission for Science, Technology and Innovation (NACOSTI):** mandated to regulate and assure quality in the ST&I sector, set ST&I priorities for Kenya, and advise the government on related matters.
- **Kenya National Innovation Agency (KENIA):** mandated to develop and manage the national innovation system by strengthening linkages between research institutions, the private sector, and government entities.
- **National Research Fund (NRF):** mandated to mobilize and manage financial resources for the advancement of the national innovation system, based on priorities set by NACOSTI.

Many respondents pointed to significant challenges faced by these government entities. As a newly established body, NACOSTI's role in coordination of R&D is still evolving. Its authority as lead R&D regulator, however, has been undermined by parallel government funding sources that allocate research money directly to subordinate institutions; and NACOSTI itself is underfunded. Though KENIA and the NRF are not yet operational, all three entities appear to have a degree of overlapping functions. Additionally, NACOSTI, KENIA, and the NRF all sit within the Ministry of Education, Science and Technology (MOEST); this ministry oversees education in Kenya, which has resulted in the de-prioritization of important R&D and regulatory

issues in favor of more politically pressing and visible education issues.

According to interviewed stakeholders, the regulatory process in Kenya faces similar challenges in terms of coordination. While NACOSTI provides regulatory oversight, the Pharmacy and Poisons Board (PPB) 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 and the Kenya Bureau of Standards. The number of government entities involved in regulation contributes to the long and complex regulatory pathway that research institutions, the private sector, and other innovators

must navigate. Preclinical trials, for example, require research permits from six different regulatory agencies.

Finally, an accountability mechanism by which to track government commitments to health R&D is needed; stakeholders noted that there is no open data platform to view current expenditure on health R&D and progress toward policy implementation. Limited transparency and inefficient fund management systems have led to the mismanagement of external donor grants to government entities. Increased transparency and policy implementation would make the health R&D system easier to navigate, enabling researchers to spend more time focusing on innovations for health impact.

TABLE 1. Kenyan policies that govern health R&D	
The Constitution of Kenya (2010)	Kenya’s constitution provides an overarching legal framework to ensure a comprehensive, rights-based approach to the delivery of health services and protects intellectual property rights to stimulate product development.
Kenya Vision 2030	As the national blueprint for development, this policy aims to transform Kenya into an industrialized, middle-income country by 2030. It recognizes the role of R&D in accelerating economic development and commits to increased government funding so that Kenya becomes a regional center for R&D of new technologies.
The Kenya Science, Technology and Innovation Act (2013)	The Science, Technology and Innovation (ST&I) Act provides a framework for promotion, coordination, and regulation of the ST&I sector, and mandates a government allocation of 2 percent of GDP to R&D. The Act also establishes three government bodies with complementary mandates: the National Commission for Science, Technology and Innovation (NACOSTI), the Kenya National Innovation Agency (KENIA), and the National Research Fund (NRF).
Ministry of Education, Science and Technology Strategic Plan (2013–2017)	This plan was developed to streamline the ministry’s activities and is aligned with Vision 2030. It sets out strategic objectives for the ministry, which include strengthening ST&I capacity and increasing national budget allocation to 2 percent of GDP.
The Pharmacy and Poisons Amendment Bill	The Pharmacy and Poisons Amendment Bill is still in draft form. If adopted, it would replace the Pharmacy and Poisons Board, which regulates and registers medicines, with the Pharmacy and Poisons Authority (PPA). The PPA would have expanded oversight, including quality assurance, packaging and distribution of medicine, licensing for distribution, and clinical trial approval.
The Health Bill	This draft legislation provides guidance on health system management at the national and county levels. If adopted, the bill would establish a single regulatory body for health products. It also earmarks 30 percent of R&D funding from GDP specifically for health.

Investing in health research and development

Insufficient accountability measures have contributed to low government investment in R&D generally, and health R&D specifically. Despite international and regional commitments to increase spending, including a 2007 African Union pledge to allocate 1 percent of GDP to R&D, Kenyan spending on R&D hovers around 0.5 percent. The ST&I Act goes beyond this commitment, mandating a 2 percent allocation of GDP to R&D. According to many of those interviewed, however, current policy and strategic plans do not provide an adequate road map for reaching the 2 percent commitment.

External donors provide the majority of R&D funding in Kenya; domestic spending accounts for less than one-third of national expenditure on R&D. Coupled with an absent national health research agenda, donors largely drive R&D priorities, which may not accurately reflect Kenya's most urgent health needs. According to stakeholders, opportunities for innovators to tap into alternative funding mechanisms, such as venture capital, are minimal, and private-sector financing of health R&D is low. Meeting current funding commitments and ensuring the availability of resources for local innovators will help grow Kenya's R&D sector and ensure that R&D priorities are locally generated.

Strengthening the innovation culture

A dearth of alternative financing options and a hard-to-navigate regulatory system have contributed to a weak innovation culture in Kenya. Many stakeholders raised concerns about the low number of health products that are introduced and scaled up, as well as a significant focus on testing health products developed elsewhere. Fear about intellectual property (IP) rights contributes to these shortfalls; low awareness of the IP management process and inaccurate information about patent filing and ownership reduce the confidence of innovators and funders, and lead researchers to work in silos. Additionally, university staff are not impelled to engage in research, as their career success is largely determined by number of publications authored, rather than the production of tangible health products.

Furthermore, there are no tax incentives to encourage R&D activities, spur private-sector engagement, or promote local pharmaceutical manufacturing. Many stakeholders felt that policy instruments to incentivize innovation will be key to strengthening the R&D sector in Kenya.



PATH/Wendy Stone

Increasing technical skill and capacity

Many government entities that have a mandate related to health R&D are under-resourced, in terms of funding, staffing, or technical skill. Stakeholders highlighted low staff numbers at NACOSTI and PPB; for example, just one pharmacist is responsible for regulating all imported pharmaceutical products, though imports represent 70 percent of the pharmaceutical market. Understaffing also contributes to long delays in the research permit process.

Additionally, many of those interviewed highlighted inadequate technical capacity for the regulation of medical devices and digital technology. Because there is no quality assurance reference for medical devices and equipment, researchers rely on external standards, such as the US Food and Drug Administration. Investment in the technical capacity of government entities and research institutions will be critical in accelerating the discovery or invention of new health technologies.

Bolstering the local pharmaceutical industry

Kenya does, however, have a reasonably strong capacity for the local manufacture of pharmaceutical products and a well-developed system for pharmacovigilance. Current export of locally manufactured pharmaceutical products is already at 50 percent, and initiatives such as the East African Community (EAC) Medicines Regulatory Harmonization (MRH) will likely provide additional market opportunities in neighboring countries.

Unfortunately, stakeholders identified gaps in implementation of policy provisions for preferential procurement of locally manufactured goods, contributing to an unfavorable domestic market. Many imported products are cheaper than local equivalents, and because of high out-of-pocket health expenditure, there may be an inclination to opt for cheaper medicines.

Most manufacturers do not have access to affordable financing to upgrade their facilities to meet WHO pre-qualification standards, meaning that international mechanisms like the Global Fund to Fight AIDS, Tuberculosis and Malaria and Gavi, the Vaccine Alliance, will not procure their products. Many stakeholders agreed that preferential procurement from the government would incentivize health technology development and production.

POTENTIAL POLICY SOLUTIONS

Despite the challenges faced by Kenya's national health innovation system, potential policy solutions exist for creating a more enabling environment for health R&D and regulatory. Recommendations include:

- *Improving financing for health R&D.* MOEST should strengthen and implement the strategy in its 2013-2017 Strategic Plan to increase government investment in R&D to 2 percent of GDP. Additionally, a percentage of R&D funding should be set aside specifically for health. In order to promote transparency, the government should institute an open data platform to track health R&D expenditures. Finally, alternative funding mechanisms for health innovations should be explored.
- *Increasing efficiency of government entities.* Through policy alignment and clarification, as well as budget commitments, government institutions overseeing, funding, and regulating health R&D processes should have clear, complementary mandates, and should be adequately staffed. Research approval processes should also be streamlined, and the EAC MRH initiative should be prioritized as a method of sharing best practices and fast-tracking registration of medicines for priority diseases.
- *Strengthening capacity for health innovators, researchers, and institutions.* The government should prioritize policies and initiatives that increase the technical capacity of research institutions and individual innovators. Additionally, collaboration between researchers should be promoted, and health R&D activities should be incentivized.

- *Improving the policy environment for health R&D.* Ultimately, the government should seek to strengthen the policy environment for health R&D by aligning and implementing existing policies, creating mechanisms to encourage participation in R&D for health, and developing a national health research agenda to guide research and funding priorities.

A PATH FORWARD

Through a coalition of advocates and technical experts from across the health spectrum, PATH is advocating for increased investment, improved policies, and streamlined regulatory processes that support the development, introduction, and scale of high-impact health technologies. By creating an enabling policy environment for health R&D and encouraging innovation, Kenya can pursue solutions that reflect its greatest health needs.



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