

Research and Development for Health in South Africa

Landscape analysis executive summary

INTRODUCTION

The investment in health research and development (R&D) by low- and middle-income countries (LMICs) 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 and priorities.

The government of South Africa has demonstrated commitment to health R&D, passing a number of policies and strategies aimed at bolstering the country's innovation agenda. Many government departments and institutions have been created and tasked with funding, regulating, and participating in health R&D. Additionally, government funding for health R&D has increased over the past decade and has met an important international commitment to direct 2 percent of the national health budget to R&D. With strong infrastructure, existing policies, and financial backing, South Africa is well positioned to reap the economic benefits of a robust R&D sector.

Key barriers, however, prevent South Africa's innovation ecosystem from reaching its full potential. To better understand the challenges impacting health R&D and identify potential solutions, PATH commissioned the Council on Health Research for Development (COHRED) to conduct a landscape of policies, advocacy initiatives, stakeholders, and funding trends related to health R&D and regulatory processes.

In a consultation with stakeholders from across the innovation landscape, many noted that the implementation of important R&D-related policies has been slow, and greater government investment is needed to support innovation across the value chain, from research and design to introduction and scale-up. Despite the numerous government departments and agencies involved in health R&D, coordination and delineation of roles remain a challenge. Additionally, some researchers and innovators have difficulty accessing available resources, and increased transparency is needed in the decision-making processes of government entities that oversee funding and regulatory approval. By removing these barriers, the South African innovation system will be better able to translate science,

research, and technology development into economic growth and a higher quality of life for its people.

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

Through COHRED's literature review and consultations with R&D policy experts and stakeholders, four overarching challenges impacting health R&D in South Africa emerged. This document summarizes these key challenges and other findings, and identifies potential solutions that could be the focus of future policy advocacy efforts.

Governance and commitment to R&D

The South African government has created a strong policy framework to guide the country's innovation system (Table 1), and it supports many robust departments and agencies that manage, coordinate, and fund R&D. The Department of Health (DOH), Department of Science and Technology (DST), and Department of Trade and Industry (DTI) all have roles and responsibilities related to health innovation and oversee key research and funding entities:

- **Medical Research Council (MRC):** As part of the DOH, the MRC leads health research and provides funding to other institutions, including clinical research.
- **Strategic Health Innovation Partnership (SHIP):** Through DST and DOH collaboration, SHIP acts as a funding mechanism within the MRC to enhance R&D capacity and facilitate research and technology transfer.
- **Medicines Control Council (MCC):** A DOH entity that is responsible for regulating medicines and clinical trials in South Africa. In November 2015, parliament passed legislation that will replace the MCC with a new independent, public regulatory agency.
- **National Research Foundation (NRF):** As part of the DST, the NRF provides funding for basic research directly to universities and designated research entities.
- **Technology Innovation Agency (TIA):** A DST funding mechanism that supports the development and commercialization of technology.

In order to provide an overarching vision and mandate for the government’s role in creating a world-class biotechnological innovation system, South Africa passed the Bio-Economy Strategy, which aligned many of the above entities. The strategy also created SHIP and TIA, and it revitalized and restructured the MRC. Stakeholders interviewed for this landscape noted that SHIP has been successful in improving coordination of funding for health R&D projects. Additionally, SHIP has attracted international funders, who benefit from its location within the MRC and resulting low overhead costs. Conversely, stakeholders pointed to significant gaps in TIA’s ability to fund product development and commercialization activities, as it has been plagued by claims of mismanagement and poor decision-making, as well as a number of politically appointed board members who lack expertise in health R&D.

Despite the strengthening of some institutional collaboration through SHIP, many stakeholders pointed to overlapping mandates of government departments, as well as gaps in coordination. The DOH, for example, is tasked with promoting health research, while the DST provides

leadership, resources, and an enabling environment for science, technology, and innovation; there is a draft agreement between the two departments on roles and responsibilities each has in relation to health innovation, but it has not yet been finalized.

Furthermore, broader policy conflicts and inconsistencies have impacted the growth of South Africa’s health R&D sector. The implementation of the Bio-Economy Strategy has been slow, and stakeholders noted the absence of a detailed, costed implementation plan. An interdepartmental coordinating committee was meant to guide and monitor implementation, but it has not yet been established. There has also been uncertainty about the intellectual property (IP) rights of researchers and innovators, as new legislation—a Draft National Policy on Intellectual Property— includes a compulsory licensing provision that would allow the government to acquire or restrict patent rights without having to compensate IP owners. In strengthening the R&D sector in South Africa, critical policies coordinating the roles and responsibilities of R&D stakeholders must be implemented to ensure that the policy environment enables research and innovation.

TABLE 1. South Africa policies that govern health R&D	
Ten-Year Innovation Plan (2008)	This plan seeks to establish a knowledge-based economy in which discoveries in science and technology lead to economic benefits for South Africa. It establishes the “Farmer to Pharma” value chain, which aims to leverage the country’s biodiversity, human capital, and indigenous knowledge to spur biotechnological innovation.
Bio-Economy Strategy (2014)	The Bio-Economy Strategy is the DST roadmap for research, development, and innovation in South Africa. By bolstering the health, agriculture, and industry sectors, it aims to ensure that the bio-economy contributes 5 percent to South Africa’s GDP by 2050. It outlines key mechanisms for coordinating innovation efforts so that stakeholders can contribute—rather than compete—for opportunities, resources, and outcomes.
Medicines and Related Substances Amendment	This amendment to the Medicines and Related Substances Act of 1965 will replace the MCC with a new independent, public regulatory agency called the South African Health Products Regulatory Agency (SAHPRA). SAHPRA will regulate all medicines and clinical trials, as well as medical devices. The draft amendment was passed by Parliament in November 2015, but requires the president’s signature before becoming law.
National Health Research Policy (2001)	The National Health Research Policy creates a framework for a multidisciplinary health research system to ensure that all South Africans have access to effective and efficient health services. It also seeks to build research capacity for the community, health service providers, research institutions, and decision-makers.
Draft National Policy on Intellectual Property	First introduced in 2013, this draft policy would amend the 2008 IP Act. It includes a compulsory licensing provision that would allow South Africa to acquire or restrict patent rights without having to compensate IP owners.

Regulatory environment

The regulatory environment in South Africa is equally complex, and many stakeholders interviewed cited difficulty in obtaining the licenses and permits needed for health R&D. Researchers must apply to a number of institutions for clinical trial approval, and the application and approval process often lack transparency. The MCC, which is responsible for regulating medicines and clinical trials, offers limited guidance on requirements for a successful application, resulting in the rejection of applications on technical grounds, as well as prolonged delays. Some stakeholders reported that personal relationships with MCC staff can greatly help in navigating the system. Additionally, there is no formal enquiry or complaint system at the MCC.

Many of these delays and backlogs can be attributed to insufficient staff and resources; the R&D industry in South Africa has grown significantly, but the MCC has not grown with it. With a limited in-house staff of 100 people, the MCC heavily relies on experts from academic institutions to review applications. Additionally, the MCC has been flooded with approximately 300 generic medicine applications each year, and registration can take two to three years. This backlog has been exacerbated by applications from other countries in the region, as MCC registration is recognized in neighboring countries.

To solve the problems faced by the MCC, Parliament recently passed an amendment to the Medicines and Related Substances Act of 1965, which will replace the MCC with a new independent, public regulatory agency called the South African Health Products Regulatory Agency (SAHPRA). SAHPRA will regulate all medicines and clinical trials, as well as medical devices. SAHPRA's establishment is positively anticipated, but many stakeholders expressed concern about its capacity. The new regulator will have an expanded mandate, but will build capacity for this mandate over a multiyear period. Moreover, there has been a lack of transparency in developing the implementation plan. After the president signs the amendment into law and the transition to a new regulatory authority begins, it will be critical to ensure that SAHPRA has the capacity and resources needed to effectively provide regulatory oversight.

Investment in and incentives for R&D

Investment in health R&D from the public and private sectors has increased significantly; health R&D now accounts for 17 percent of overall R&D expenditure, up from 13 percent a decade ago. Government spending specifically has increased sharply over the last three years. The government is also meeting the 2008 Bamako Agreement, an important international commitment to direct 2 percent of the national health budget to health R&D. More



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information is needed, however, to understand where this money is being invested.

Despite increasing government investment, stakeholders recommended greater coherence across government departments to ensure that health R&D is funded across the value chain, from research to scale. Financing mechanisms to support commercialization are also needed; private venture capital for commercializing health innovations has been limited and is ill-suited for the long timelines and high costs of R&D. TIA is the government entity responsible for funding commercialization, but plans to establish a government-backed venture capital fund through TIA were stalled by concerns about the agency's effectiveness. Funding partnerships between government entities and international investors, however, have been successful; SHIP's low operating overheads make it an attractive vehicle for international funding of R&D projects.

Beyond funding, robust incentives to encourage private-sector participation in health innovation are also important in stimulating the R&D sector. The government enacted an R&D tax incentive, which allows for tax deductions of 150 percent for R&D expenses and an accelerated depreciation for spending on related machinery and equipment. Those seeking this deduction, however, reported that the application process is administratively burdensome, as applications must be reviewed by multiple government departments with varying levels of expertise and discordant mandates, and requirements are applied inconsistently. Moreover, there is little transparency in the decision-making process. Tax incentives are also available to promote local manufacturing, but MOH procurement of locally manufactured products needs to be strengthened. Locally manufactured technologies have the potential to reduce overall health system costs and strengthen the economy, but they often cost more up-front. Some interviewees reported that the MOH does not see its responsibility in financing the industrial and economic mandate of the DTI and does not prioritize preferential procurement of locally manufactured products. Ultimately, incentives for innovation and manufacturing will be key to strengthening the R&D sector in South Africa.



Technical skills and capacity for R&D

South Africa has a robust infrastructure for R&D, and many of its universities and science councils have attracted international investors. The MRC, for example, recently secured a research partnership with the United States National Institutes of Health, which will expand basic, translational, behavioral, and applied research to advance scientific discovery in HIV/AIDS and tuberculosis, as well as HIV/AIDS-related cancers. The growing community of researchers and scientists in South Africa have strong capacity in basic research, clinical trials, and bringing commercialized products to market.

Many stakeholders, however, stated that more emphasis should be placed on commercializing products and scaling up local manufacturing. South African drug companies are mostly limited to reformulation or repackaging of medicines and active pharmaceutical ingredients (APIs); there is little capacity for producing APIs at scale. Additionally, South Africa has inadequate trade protection against foreign competitors in the medical product industry and therefore relies heavily on imports, including 65 percent of pharmaceuticals, 90 to 95 percent of devices, and 100 percent of diagnostics. Stakeholders noted that there is, however, significant room for growth. Though South Africa accounts for under 1 percent of the global pharmaceutical market, it makes up a quarter of the antiretroviral market in LMICs. Regional harmonization efforts hold additional long-term opportunities for expanding the marketplace for locally manufactured medicines and products.

Finally, an enabling policy environment that incentivizes health R&D and reduces barriers for regulatory approval would encourage more South Africans to pursue innovation through start-up activities. Entrepreneurship and new health technology companies are critical in commercializing health

products, but the costs and barriers to obtaining regulatory approval and patent registration often seem prohibitive. Uncertainty among researchers and innovators about the future of the IP policy is also problematic.

POTENTIAL POLICY SOLUTIONS

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

- *Strengthening the policy environment for health R&D.* For the economic and social benefits of health R&D to be realized, existing policies must be aligned and fully implemented, and mechanisms must be created to encourage participation in R&D for health. Specifically, the implementation plan for the legislation creating SAHPRA should be made public, and an ombudsman should be appointed to ensure transparency.
- *Improving financing for health R&D.* Funding mechanisms must be coordinated and able to support health R&D across the value chain. To this end, alternative financing mechanisms for the commercialization of health technologies, including venture capital funds, should be explored. Additionally, the government should improve access to funding for researchers and innovators and reduce barriers to obtaining tax incentives.
- *Bolstering civil society engagement in health R&D.* Civil society can play a critical role in holding the government accountable to commitments and ensuring that health R&D-related strategies are implemented. Civil society has long called for improved access to health care in South Africa; by mobilizing around this issue, they can increase political will to create an innovation system that will not only improve health outcomes, but also encourage economic growth.

A PATH FORWARD

Through a coalition of advocates and technical experts from across the health spectrum, PATH and partners are advocating 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 R&D and encouraging innovation, South Africa can advance solutions that tackle its greatest health needs.



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