FIVE

Frugal and reverse innovation in the medical devices industry in South Africa

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INTRODUCTION

The medical devices industry plays a critical role in the healthcare system of a country, particularly in the prevention, diagnosis and treatment of various diseases as well as in patient monitoring (Chandan et al., 2021). There are more than 10,000 different types of medical devices globally at varying degrees of complexity and cost, including surgical instruments, medical imaging devices, in-vitro diagnostics, and prostheses (WHO, 2011; Kale and Wield, 2019). However, most medical devices in low- and middle-income countries (LMICs) have been designed for use in high-income countries (Marks et al., 2019). The World Health Organization has reported that LMICs have lagged

in the development and manufacturing of medical devices, particularly ones appropriate to and affordable in local contexts (WHO, 2012; 2016). Instead, these countries depend on imported medical devices, most of which are costly and/or incompatible with local settings and socioeconomic dynamics (Marks et al., 2019).

South Africa has an emerging medical devices manufacturing sector, which is mostly limited to assembly and lower-end products, with a few exceptions (Fitch Solutions, 2021). South Africa's medical devices industry is largely dependent on imports. Moreover, the number of start-up medical device manufacturers in the country has been declining (Maharaj and Sunjka, 2019). There has, however, been a rising interest in the medical device industry in South Africa in the past few years, which was deepened by the unfortunate realities exposed by the Covid-19 pandemic. The pandemic laid bare the importance of robust innovation and production capability in the key area of medical devices to ensure greater resilience and sustainability in health systems, and to enable a more agile response to public health crises. The need to localise the manufacturing of medical devices became even more urgent. Aside from the benefits of having context-specific medical devices, many see the medical devices industry in South Africa as an opportunity for economic growth, job creation, localisation, a reduction of trade imbalances and a reduced reliance on imports (SAMRC, 2022).

However, the research and development of medical devices is capital intensive; there is inadequate funding and government support across the full value chain; and there is unclear market guidance for and pathways to commercialisation (SAMRC, 2022). These are some of the challenges faced by medical device firms and the reasons some of their technologies fail to reach commercialisation.

This chapter examines the kinds of medical devices that have been successfully commercialised in South Africa and the conditions under which this occurred. It also explores the contribution of medical innovation to the country's development goals, particularly Chapter 10 of the National Development Plan (NDP, 2013). Additionally, the chapter discusses how some so-called 'frugal innovations' in healthcare extend their journeys to more developed countries, thus

becoming 'reverse innovations'. Low- and middle-income countries have increasingly been providing new sources of global innovation, and thus offering firms worldwide fresh opportunities for innovation. The location and focus of innovation have become broader and there is a need to adjust innovation management theories, models and frameworks. The theoretical foundation for the analysis is drawn from innovation literature, particularly frugal and reverse innovation as well as national health innovation systems literature.

Through exploring the journey of three South African medical device innovations, this chapter expands the discussion on the role of innovative medical device manufacturing firms as sources of frugal product innovation. The chapter also identifies the determinants and consequences of, and agents involved in, reverse innovation for medical technologies. Importantly, the chapter draws attention to the critical role of government and strong health systems in advancing innovations for public health. In this respect, the chapter argues for a broader analytical lens with closer attention paid to access and societal impact.

FRUGAL AND REVERSE INNOVATION

This chapter explores the notions of frugal and reverse innovations, which have similar characteristics but also clear differences. These concepts are adopted as useful analytic lenses through which to view the case studies that will follow in later sections. 'Frugal innovation' is the term used for innovations intended for markets in emerging economies, typically designed with consideration for the contexts in these markets. This means that consideration is given to factors such as the need to keep costs low, and to concentrate on core functionalities and optimal performance (Weyrauch and Herstatt, 2017; Zeschky et al., 2014). Frugal innovation may take place outside of emerging economies but it is certainly directed at consumers in developing countries or indeed poorer consumers in developed countries. Previously, the term frugal innovation was used to describe a context in which there is a lack of resources for development and affordable prices for intended customers. In its current formulation, however,

it is applied to a population's unsatisfied demands and to needs left unaddressed by established institutions (Bhatti and Ventresca, 2013). Frugal innovations thus also contribute to addressing social needs, such as the provision of healthcare, at more affordable prices (Rosca et al., 2017). Harris et al. (2020) found that the term 'frugal' took on added meanings in the course of the Covid-19 pandemic: they report that it was applied to the repurposing, reusing and rapid deployment of new technologies.

The concept of reverse innovation was theorised by Immelt et al. (2009). It offers different insights into product flows and associated innovations in a globalised world. Reverse innovation is 'any type of global innovation that, at some stage during the innovation process, is characterised by a reverse flow of innovation from a developing country to an advanced country, and that is eventually introduced to an advanced country's market' (Von Zedtwitz et al., 2015). While the term challenges the notion of high-income countries as best at innovating and the initiators of healthcare transformation, it is also thus a term that can seem paradoxical; on the one hand, it challenges the notion of high-income countries as being the only sources of innovation and healthcare transformation, but the term 'reverse' also perpetuates exactly this notion.

HEALTHCARE SYSTEMS AND HEALTH INNOVATION

A healthcare system may be seen as an innovation system in which performance depends on the quality of the relationships between the people and institutions within the system. A national health innovation system is a sectoral innovation system which comprises varied actors and associated expertise (Consoli and Mina, 2009). For that reason, the definition of a health innovation system is wide-ranging, and its outcomes include new drugs and devices as well as clinical services (Djellal and Gallouj, 2005; Pammolli et al., 2005).

The fields of innovation systems and global health policy merged in the mid-2000s following considerable emphasis on the role of science in advancing new drugs, vaccines and diagnostics in solving the world's health problems (Cassiolato and Soares, 2015). The ability to improve

the health of individuals depends on much more than new discoveries or having the tools or the medications to diagnose or treat diseases. Noticeably, it also requires the healthcare system to have the ability to absorb and roll out new technologies through existing services with minimal disruption and maximum effect. Consoli and Mina (2008) highlight that in seeking to make a system effective for the provision of healthcare, it is necessary to incorporate a number of activities, skills and different types of technical and practical knowledge. All of these require effective mechanisms of coordination to achieve the overall goal of patient care (Consoli and Mina, 2008).

The concept of a health innovation system therefore includes broader aspects of institutions, standards and procedures within a national innovation system, particularly those that are connected to the provision of healthcare, including financing and research (Cassiolato and Soares, 2015). Specifically, the health innovation system involves actors that co-create value through their interconnections to achieve sustainable healthcare improvements through innovation and technology development. The degree of innovation in healthcare is highly dependent on a national health innovation system (Proksch et al., 2019).

All this means that in order to strengthen its healthcare system, South Africa must also strengthen its national health innovation system. There are some shared challenges between the two. The burden of diseases such as HIV/AIDS, TB and non-communicable diseases (such as cardiovascular diseases, diabetes, cancer and chronic respiratory diseases) is detrimental to society and perpetuates the socioeconomic marginalisation of mostly black people. As a result of its colonial and apartheid history, South Africa is reportedly the most unequal country in the world (World Bank, 2022) representing what is often referred to as a dual economy, where one economy has features of a relatively advanced capitalist economy and the other is under-developed and underfunded (Vollrath, 2009). This dichotomy is prominent in the country's healthcare system. Its private healthcare is known for its world-class facilities and care provision that is equal to that of many high-income countries. This coexists with a public healthcare system that supports 84 per cent of the population, which is

acutely under-resourced, overloaded and fails to meet its undertaking for accessible quality healthcare (Mayosi et al., 2012; MISTRA, 2019). In South Africa, as globally, there is increasing emphasis on strengthening the healthcare system by supporting the 'building blocks' of health infrastructure, which includes technologies (MISTRA, 2019). There are however the same challenges of inequality: most of South Africa's population has very limited access to technology, as well as to quality healthcare.

THE MEDICAL DEVICE INDUSTRY IN SOUTH AFRICA

South Africa, with its emerging local medical devices manufacturing sector, provides an appropriate setting for research into medical device manufacturing firms as sources of frugal (and sometimes reverse) product innovation. Despite being an upper-middle-income country, South Africa shares similar institutional and structural challenges and pressures to balance economic growth and social development. Countries on the continent all face difficulties in taking innovations to market. This challenge is particularly marked in South Africa as it has world-class biomedical research. Nonetheless, the country has few companies that have successfully commercialised their products (Chakma et al., 2010; SAMRC, 2022). The sector is dominated by multinational corporations, represented by the South African Medical Device Industry Association, selling mainly imported products. Local medical device manufacturing is represented by Medical Device Manufacturers of South Africa.

The South African medical device manufacturing industry is active across a range of fields and device classes. A survey led by the South African Medical Research Council (SAMRC) revealed that South Africa has at least 136 medical device manufacturing companies with substantial diversity in sizes, turnovers, products and levels of R&D expenditure (SAMRC, 2022). Over half (53 per cent) of the survey respondents operate in the consumables field, followed by 27 per cent in the orthopaedics sector, and 14 per cent in hospital furniture; the remaining 21 per cent operate in assorted other fields. The industry produces and sells a variety of consumable medical device products

ranging from medical devices for wound care to diagnostic test kits. The sector is concentrated in three provinces, with most medical device manufacturers being located in Gauteng (60), followed by the Western Cape (47) and KwaZulu-Natal (26). There has been a declining trend in company formation since 2004: more than half of the companies are older than 20 years and only seven new companies were founded in the period 2015 to 2019.

South Africa's medical devices manufacturing sector is one of the largest medical device sectors in the Middle East and Africa region. It was estimated at R21 billion in 2021 and is projected to grow to R29.6 billion by 2025 (Fitch Solutions, 2021). However, this makes up only 0.3 per cent of the global market for medical devices. Government is the major purchaser of healthcare equipment and supplies in South Africa for the public healthcare sector which comprises 7,901 facilities with 85,362 registered beds (Who Owns Whom, 2019).

CASE STUDIES: SOUTH AFRICAN MEDICAL DEVICES

Although frugal innovations in healthcare have been studied (Arshad et al., 2018), more research needs to be conducted on the commercialisation and successful diffusion of frugal innovations through public healthcare, locally and abroad. Furthermore, it is crucial to expand the discussion on the contribution of medical innovation to South Africa's development goals in the area of health. This section discusses three case studies of firms in South Africa that have successfully designed and introduced medical device innovations into the market. Specifically, the section focuses on medical devices from these three firms to provide insight into the conditions that lead to the development of medical innovations in South Africa; the kinds of medical devices that are successfully commercialised; and the support required for the medical devices to thrive, and, in some cases be adopted, abroad.

Case Study 1: The Sinapi chest drain

Background and context: The problem of gun violence in South Africa is among the most acute in the world, with gun-related deaths estimated at

20 per day (Masters et al., 2021). Penetrating chest trauma (injuries such as gunshot and stab wounds) is one of the leading causes of admission to South African emergency departments (Keegan, 2005; Masters et al., 2021). This results in excessive pressure on trauma facilities with associated cost implications. It is thus valuable to have these traumas effectively and efficiently managed to ensure short hospital stays and minimal complications. For years, cases of pneumo-/haemothorax[1] (the condition of having air (pneumothorax) or blood (haemothorax) in the chest cavity) have been treated using standard underwater bottle drainage. An underwater seal chest drainage system is used to re-establish correct air pressure to the lungs, re-inflate a collapsed lung as well and remove blood and other fluids (Zisis et al., 2015). The Sinapi chest drain was launched by Sinapi Biomedical to provide a more cost-effective treatment than with existing chest drainage systems (Cooper and Hardcastle, 2006).

The firm: Sinapi Biomedical is a Stellenbosch-based medical device firm that focuses on providing the most affordable possible products (Devex, 2023). It is owned and managed by a mechanical engineer with diverse industrial experience and has been fully operational since 2006 (Sinapi, 2020). The firm has advanced engineering and manufacturing capabilities, with over 150 people in its employ and it frequently collaborates with academic institutions, either the relevant Engineering Department or the Medical School at Stellenbosch University (Sinapi, 2020; Devex, 2023). Since its establishment, Sinapi has successfully commercialised several affordable products, such as its chest drain, aimed at improving access to healthcare in South Africa and other developing countries (Sinapi, 2020; Devex, 2023).

Medical device: The Sinapi chest drain is an external medical device made of plastic that incorporates a fluid reservoir, a one-way valve and an air-leak detection system (Cooper and Hardcastle, 2006). It is connected to a thoracic intrapleural catheter to allow fluid and air to drain from the thoracic cavity. The Sinapi chest drain incorporates a mechanical (Scheffler) valve, which allows for faster evacuation

1 A haemothorax, pneumothorax, or the combination of both (haemopneumothorax) can occur as a result of a wound to the chest, such as from a bullet, stabbing, or broken rib.

of liquids and air from the chest, makes patient management easier and supports early patient mobility (Cooper and Hardcastle, 2006). The advantages of a Sinapi drain over a standard underwater bottle drainage include: a) a smaller, lighter device, which facilitates greater patient mobility and comfort; b) a 'closed system' fluid drainage that protects nursing staff from exposure to body fluids; and c) fast, easy attachment to any size chest catheter without the need to add water (Cooper and Hardcastle, 2006).

Frugality: The Sinapi chest drain was developed to provide a more affordable way to manage trauma injuries. The technology costs less than R300 (approximately US$15 at time of writing) (Hardcastle, 2021); only one Sinapi chest drain is required for a patient's entire hospital stay because it can be emptied rather than be replaced (Sinapi, 2022); removing the need for bottle changes also reduces sterilisation costs, In addition, a clinical trial showed that the Sinapi chest drain has an average drainage time of 61.04 hours compared to 81.47 hours with a standard underwater seal (Hardcastle, 2006). This means a patient's hospital stay is reduced, resulting in further cost savings. The Sinapi chest drain can thus be considered a frugal innovation.

Reverse innovation: The Sinapi chest drain carries the CE marking, which indicates that a product has been deemed to meet European Union (EU) safety, health and environmental protection requirements. It is required for products marketed in the EU manufactured anywhere in the world, and it thus facilitates access to the European market and free movement throughout the European Single Market (BSI, 2023). The Sinapi chest drain is currently exported to Europe.

Case Study 2: The Medical Diagnostech Covid-19 Rapid Screen Test

Background and context: The Covid-19 pandemic exposed the deficiencies in medical device manufacturing supply chains and distribution models, which resulted in shortages of testing reagents, diagnostic test kits, personal protective equipment and respiratory devices. The supply of Covid-19 diagnostics became a concern, particularly for low- and middle-income countries. In order to address this shortage in South Africa, the SAMRC partnered with the South

African government, academia and business to provide support for the development and scaling up of local reagents and point-of-care tests for SARS-CoV-2. This was to ensure rapid and robust options for South Africa with locally produced diagnostics and reduced dependence on international provisions. Medical Diagnostech was one of the enterprises to receive funding to develop and supply antigen-based test kits for the management of Covid-19 in South Africa.

The firm: Medical Diagnostech (Pty) Ltd was established in 2010 as a developer and manufacturer of lateral flow rapid diagnostic test kits. The firm manufactures rapid diagnostic test kits using its trade-secret methodology for increased sensitivity and early detection. Lateral flow tests are manufactured under ISO 13485[2] accreditation and include tests for alcohol consumption, drugs of abuse, HIV, malaria, pregnancy, fertility/ovulation and Covid-19. Medical Diagnostech also offers manufacturing and development services for innovative lateral flow components and test kits, as well as other medical-related products including sanitisers and surgical scrubs. The firm has an in-house laboratory with a three-member R&D team and makes use of student interns from the University of the Western Cape (Chakravarty, 2022).

Medical device: Medical Diagnostech's rapid antigen test, the SARS-CoV-2 Antigen Device, is a rapid visual immunoassay for the qualitative detection of the Covid-19 nucleocapsid protein (N-protein) antigen from nasopharyngeal swabs (HealthPulse, 2022). It is intended for professional use to diagnose acute infection and reveal the patient's current infection status. The Medical Diagnostech rapid antigen test was approved by South African Health Products Regulatory Authority (SAHPRA) in December 2021 (SAMRC, 2022). Since then, Medical Diagnostech has partnered with Audere, a digital health non-profit organisation, which produces tech-based solutions to delivering health equity in underserved communities worldwide (Audere, 2022). This partnership has resulted in the launch of a self-test version, in combination with the mobile phone application, HealthPulse TestNow: South Africa's first Covid-19 antigen self-test (SAMRC, 2023). The

2 ISO 13485 is the medical industry's optimal medical device standard, which ensures that all medical devices meet the proper regulatory compliance laws and customer needs.

application provides detailed instructions on how to perform the self-test and assists in interpreting the results through image capture of the rapid test device (SAMRC, 2023).

Frugality: Medical Diagnostech develops test kits that are cheaper than alternative ones. The firm focuses on the market for low-income groups, particularly in the African market, thus promoting Africa's self-sufficiency (HealthPulse, 2022). The manufacturing facility is ISO 13485 certified, complete with some equipment designed and fabricated locally to reduce costs (Chakravarty, 2022).

Reverse innovation: Medical Diagnostech targeted the South African market for its rapid antigen test. The company seemingly has no intention of marketing it outside the country; thus there is no reverse innovation achieved.

Case Study 3: The Lodox Scanner

Background and context: The diamond company De Beers faced a substantial loss of profits with some of its miners smuggling diamonds in the mid-1980s and '90s. The company's relatively advanced engineering team was asked to develop a whole-body scanner that would be able to detect even the smallest diamonds in or attached to human bodies. An X-ray body scanner was developed and used henceforth in this industry. Some of the engineers however saw potential for this innovation in the medical field too and formed a separate company to further develop this scanner.

The firm: Lodox Systems (Pty) Ltd was formed in 2002 as a result. The state-owned Industrial Development Corporation (IDC) of South Africa is the major shareholder of Lodox Systems and funds ongoing research, development and product improvements.

Medical device: Lodox developed the initial X-ray body scan further to enable a whole-body scan to be carried out at high speed (13 seconds), using only low radiation. The effectiveness and high speed of Lodox imaging significantly reduces the treatment time of patients with major injuries, allowing for imaging of a large number of patients in a very short time. The machine is used in trauma units and forensic pathology laboratories.

Frugality: The Lodox scanner was not regarded by its developers

as a frugal innovation. Rather it was recognised as an advanced technology with universal benefits. However, the Lodox scanner has some frugal aspects as described below, including that it offers a better solution than a conventional, imported X-ray scanner but at a notably lower cost (Chakravarty, 2022). Research by Rao (2013) shows that, as with the Lodox scanner, in some cases frugal innovations can be created with high technology. In an analysis by Chakravarty (2022), it was found that the costs of buying and owning the Lodox scanner are significantly lower than for conventional X-ray scanners. The reduced purchasing price is a result of lower R&D costs in comparison to high-income countries. Chen et al. (2010) found that the cost of a single-image Lodox/Statscan study is lower than the sum of multiple X-ray studies. Furthermore, the scanner can be operated by health workers with minimal training, thus there is no need for a radiologist. Lastly, the Lodox scanner requires less infrastructure (radiation proofing) and is locally manufactured, repaired and maintained, further adding to its frugal characteristics.

Reverse innovation: Lodox Systems (Pty) Ltd has various partner firms around the globe selling its scanner and a full subsidiary in Ohio, USA. Lodox installations for use in trauma units and forensic pathology laboratories can be found around the globe (North America, South America, Europe, Asia and the Middle East). In addition, the firm has obtained regulatory approval for the scanner in other countries. The Lodox scanner is thus a successful reverse innovation.

THE DETERMINANTS OF SUCCESS AND SOCIETAL RELEVANCE FOR MEDICAL DEVICES

Appropriate innovation

The three case studies show that more often than not, an important driver of successful innovation is being developed within context, meaning that there was a specific need for it in that particular market. This ensures that successful innovations are often both usable and desirable in the context for which they are designed. For example, as previously mentioned, trauma injuries are common in South Africa and thus medical innovations that assist in managing trauma injuries

are critical and in demand. The value of the Sinapi chest drain and the Lodox scanner in addressing the burden on hospitals caused by gunshot and knife wounds made their success probable. Similarly, Medical Diagnostech's rapid antigen tests were produced at a time of very high demand during the pandemic.

Relevance to context does not only make for commercial success: it can also mean that an innovation has social benefits. For example, widespread trauma injuries are often directly linked to the socioeconomic conditions of a population group. Innovations developed to alleviate such adverse socioeconomic conditions have been referred to as public interest technologies. Emulating the framework of public interest law, public interest technology aims to ensure technology is 'designed, deployed, and regulated in a way that protects and improves the lives of people, centring values of equity, inclusion, and accountability where the public interest is at stake' (Ford Foundation, 2023).

All three case studies can be considered public interest technologies. The Sinapi chest drain addresses a major problem in the South African healthcare system. So too does the Lodox scanner, even though it was initially designed to detect stolen diamonds in mines. The Medical Diagnostech rapid antigen test provided an affordable solution for South Africa at a time when there was a desperate need for urgent health responses to the pandemic.

Adoption into a healthcare system

As described previously, a country's health system is part of its broader national innovation system. However, an NIS that is functioning optimally is not enough to guarantee the adoption of a new medical technology. Rather, a country's health system has to be receptive to the technology, and have the resources for it. Crucial to this process is evidence of a technology's effectiveness, lower cost and superiority in a clinical setting in comparison to available products. Government provision of access to patients and/or clinical facilities to develop and test the prototypes offers opportunities to develop such evidence, and thus supports the technologies' introduction into the healthcare system. In the three case studies, the South African government

supported the uptake of the medical devices into the healthcare system by providing access to public research facilities and allowing for testing in public research facilities and government hospitals. For example, Groote Schuur Hospital, a public academic hospital, participated in the prototype testing and clinical trials of the Lodox scanner. Following an animal trial undertaken at Stellenbosch University in 2002, which found the Sinapi chest drain to be 100 per cent effective, samples of the chest drain were used at Tygerberg Hospital, a government hospital. Adoption of Medical Diagnostech's rapid antigen tests was ensured from the start: government recognised the extent of the need for such a test even before development was complete.

Partnerships and funding

Partnerships were key to the success of all three medical devices discussed. The University of Cape Town had a significant role in the successful development of the Lodox scanner as it collaborated with De Beers in the early phases of development when the diamond company was seeking to detect stolen diamonds. Once the value of the Lodox scanner had been proven, the Industrial Development Corporation (IDC) came on board in 2010 as a key shareholder and funder. The IDC is fully owned by the South African government and aligned with the national policy direction as set out in the NDP. The institution provided the required financial means to develop the scanners for both local and overseas markets. Moreover, government hospitals provided the local market for the scanner, with Groote Schuur Hospital testing the first prototype early on (Lodox, 2023).

For the Medical Diagnostech rapid antigen test, the South African Medical Research Council (SAMRC) – a government entity mandated to improve the health of people in South Africa through research, innovation, development and technology transfer – provided grants to assist the firm with completing the development of its testing kit (SAMRC, 2022). The grant built on existing development and the firm utilised its already-operating infrastructure, capacity and expertise to develop the Covid-19 testing kit. A collaboration that included Business 4 South Africa, the IDC and the Department of Trade, Industry and Competition (DTIC) was established to plan for downstream scale-up

and manufacturing of the testing kit (SAMRC, 2022). The firm also has an arrangement with the University of the Western Cape that allows it to recruit student interns from the university.

Sinapi receives support from the Technology Innovation Agency (TIA), a national public entity, and DTIC (Sinapi, 2023). The firm has also received some grants from international donors. However, its main sources of funds are commercial banks (Chakravarty, 2022). Sinapi has various global health partnerships and associations including one with the global health non-profit PATH (Programme for Appropriate Technologies in Health) and Grand Challenges Canada, a Canadian non-profit organisation that funds solutions to critical health and development challenges in low- and middle-income countries. Sinapi has also partnered with Stellenbosch University and Northwestern University in Illinois, USA.

In all three case studies, the relevant firms had strong partners with financial backing, as well as collaborations with local universities and hospitals. The linkages formed by these firms constitute part of a health innovation system that worked to ensure the success of their innovations. In the Lodox case, the IDC provided substantial financial backing albeit not in the early R&D phases. The rapid antigen testing kit also received financial support from government entities when Medical Diagnostech required the funds to complete development.

Firms that produce successful technology-intensive innovations often have sizable government support and strong academic connections. They are able to tap into these connections and well-established partnerships to find support for their innovations. It has thus been argued that government's role should include resource mobilisation and establishment of the conditions for widespread market commercialisation (Cozzens, 2012; Mazzucato, 2011). A lack of funding and connections has been the major downfall of many innovations.

However, in a study on medical technology firms in South Africa (Chakravarty, 2022), it was found that funds from government were not a substantial component of R&D support. Rather, support came in the form of product testing in clinical trials in academic hospitals or incubation facilities. Public research facilities and hospitals have been a

source of support and an avenue for market creation. However, many firms are unable to make it to the point at which they can receive such support: their innovations do not make it past the R&D stages due to a lack of funding. Minimal or no support in the initial stages therefore needs to be addressed, although government's involvement in taking the technologies to the commercialisation stage can be lauded.

Firm-level strategy

As much as the environment in which firms innovate is important, firms' strategies also play an important role in the success of their innovations. This is evident from the successful reverse innovations and the medical technologies discussed in this chapter. The case studies reveal that reverse innovation was intrinsic to the firms' strategies from early on. These firms have a clear strategy for the journey they desire for their medical technology innovations, from the types of partnerships they establish to the types of accreditation they pursue. Sinapi acquires the CE marking for all its technologies, which allows the firm to export to Europe. Furthermore, the company has long-term associations with international organisations such as PATH. This lays the groundwork for the firm's innovations to gain access to the international market. Similarly, Lodox has acquired FDA approval and other international accreditations. In addition, Lodox has established international partnerships and has various partner firms selling its scanner around the globe, including a full subsidiary in the USA.

In contrast, Medical Diagnostech targets the South African market, particularly the low-income groups not catered for by large companies. Seemingly, there is no immediate desire to export its testing kits and the technology will thus be an unlikely candidate for reverse innovation.

CONCLUSION

It is evident from the case studies in this chapter that medical technologies developed within the country for which they are initially intended – in this case, South Africa – solve local challenges. In-depth knowledge of a local ecosystem assists in the development of innovations within the right context. Furthermore, as has been seen

with the innovations reviewed, frugal innovations have a crucial role to play in healthcare. This is particularly the case in low- and middle-income countries but high-income countries also find value in such innovations and often adopt them in their countries.

An encouraging lesson to be drawn from the case studies in this chapter is that there is a solid foundation for a medical devices industry in South Africa, built by private firms working in collaboration with universities and other STI institutions to produce successful local innovations. These firms have both simple and complex technology capabilities and produce devices appropriate for local and sometimes export markets. The South African healthcare system, as fragmented as it is, plays an important role in the development and uptake of these medical devices.

This means that a clear avenue to boosting local innovation would be strengthening South Africa's healthcare system, to allow it to have more capacity for facilitation and adoption. As evident in the case studies, the firms responsible for successful medical innovation had access to government research facilities for prototyping and testing medical devices in a clinical environment. A strong recommendation therefore is that government takes note of the crucial role that such access plays, and takes steps to further provide it. Furthermore, testing medical devices in a clinical setting has another benefit for local innovation. Staff and patients are provided the opportunity to contribute to an ongoing culture of innovation in the healthcare system.

Another recommendation to emerge from these case studies is that government needs to come on board early in the R&D stages of the innovation process to ensure success. As discussed, it did not do so in the case of the Lodox scanner and it was evident that the company was only able to go on to successful commercialisation as it had the means to develop a prototype without government support. Existing funding instruments need to play a bigger role in the R&D stages of innovation and in continuing investment in the commercialisation of new technologies.

The importance of academia in this entire system of innovation has also been evident. A further recommendation then is that firms take the steps necessary to leverage the knowledge contained in these

institutions, including establishing academic partnerships. These connections can be an important step in converting ideas into medical products and solutions that meet customers' needs.

In general, a case can be made for government's role to include the mobilisation of resources, in academia and elsewhere, and the facilitation of the conditions for market commercialisation. Government cannot play such a role without cohesive legislative and policy frameworks to support local innovation, manufacturing and skills development. The right policies can facilitate greater cooperation and collaboration between stakeholders, and the innovation culture necessary for South Africa to build on its successes in this sector.

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