



Ministry of Foreign Affairs

Overview of the health technology sector in South Africa: Opportunities for collaboration

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OVERVIEW OF THE HEALTH TECHNOLOGY SECTOR IN SOUTH AFRICA: OPPORTUNITIES FOR COLLABORATION

Report prepared for the Embassy
of the Kingdom of the Netherlands

EXPERTS WITH **IMPACT**

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1. Executive Summary

- 1.1 FTI Consulting has been engaged by the Embassy of the Kingdom of the Netherlands to undertake a study of the health technology (“healthtech”) market in South Africa. The aim of the study is to help identify areas where Dutch and South African parties can collaborate to increase the uptake of healthtech solutions.
- 1.2 Our analysis focuses on four broad groupings of technologies: data capture; communication and knowledge transfer; consumer health technologies; and Artificial Intelligence (AI) and robotics.
- 1.3 Healthcare provision in South Africa is split between what can be broadly characterised as a well-funded private sector and a resource-constrained public sector. Both sectors present potential markets for health technology products, with some overlap and some differences in the types of technologies required in the two sectors.
- 1.4 However, the healthcare sector in South Africa is currently in a state of flux, with several processes in train that may result in huge structural changes to the sector. Most significantly, the government’s proposed National Health Insurance (NHI) programme, if implemented, will fundamentally alter the way both the public and private sector operate. At this stage, there is still much uncertainty surrounding the detail of what NHI will look like, and whether the plans will ever be put into practice. However, providers of all healthcare products and services should be starting to think about how to position themselves as suppliers to the NHI Fund, as part of their medium-term strategy. NHI opportunities will be seized by companies which are able to scale up to meet the challenge of delivering on a national footprint (and who are able to prove they can scale up).
- 1.5 Globally, the healthcare sector is thought to lag behind other industries in its use of technology by at least 10 years¹, while South Africa is also behind the curve in terms of technology adoption more generally². These facts combined suggest that the South African healthcare technology market presents significant opportunities for growth. Further, there are strong dynamics at play that will drive growth in the health technology market globally and in South Africa, including the consumerization of healthcare, pressure to reduce costs and increased focus on outcomes.
- 1.6 However, we have also identified five major barriers to greater use of technology in healthcare provision: regulatory constraints; user resistance; financing constraints; lack of appropriate solutions for the South African context; and bureaucratic decision-making processes. These present more or less significant challenges, depending on the specific subsector in question.
- 1.7 The report examines each health technology subsector, focusing specifically on

¹ Nuffield Trust (2016). *Delivering the benefits of digital health care*, Accessible at <https://www.nuffieldtrust.org.uk/files/2017-01/delivering-the-benefits-of-digital-technology-summary-web-final.pdf>

² Goldstuck, A (2019). *Fourth Industrial Revolution in South Africa*. Accessible at <http://www.worldwideworx.com/wp-content/uploads/2019/07/Exec-Summary-4IR-in-SA-2019.pdf>

growth drivers and barriers, highlighting the key players both in terms of purchasers and manufacturers, estimating the size of the market (where information is available), and identifying the most promising opportunities in the grouped sub-sectors. This analysis is based on both desk-based research and interviews with health technology experts in the private and public sectors, as well as research institutes and academia.

- 1.8 Our analysis of the markets for the individual technology subsectors is summarised in Figure 1 below, rating potential demand and existing supply in each subsector as either High, Medium or Low.

Figure 1: Priority Sector Analysis

Sector	Subsector	Demand	Existing supply	Detail
1 Data Capture	EHR	High	Medium	Private sector has begun EHR adoption. Public sector has fragmented adoption
	Routine health management information	High	Low	Once EHR systems are in place, big opportunity for analysis systems using captured data
	Vital registration	Low	Low	Never mentioned as major growth area, although may be potential for electronic death certification
2 Communication and knowledge transfer	Health knowledge management	Low	Low	Not aware of any existing solutions but also never mentioned as major growth area
	mHealth	Medium	Medium	May be overtaken by more sophisticated app-based tech. Some existing solutions (MomConnect) in market. But given infrastructure constraints, still potential for reliable low-tech solutions, esp in public sector
	Telemedicine	High	Low	Skills shortages mean lots of scope for telemedicine. Underexploited so far because of HPCSA rules, which are about to change
	Virtual healthcare	High	Medium	Complex chronic conditions require team-based management. As prevalence rises, lots of scope for technology which facilitates this
3 Consumer Health	Consumer Health Informatics	Medium	Low	Some specific opportunities related to Vitality; some other general opportunities
	Health tracking wearables	High	High	Market already mature but some potential for new brands to differentiate themselves in SA
4 Artificial Intelligence	Diagnosis and treatment decision support	High	Low	High potential demand without established players, but user adoption will be key challenge
	BIM and patient flow management	Medium	Medium	Some BIM solutions in SA market. Triage systems require better underlying data
	Advanced therapeutic technologies	High	Medium	Some technologies available but not at scale. Potential for collaboration with SA research
5 Robotics	Advanced imaging	Medium	Medium	Some local demand, depending on cost of solution, but small market. Potential for collaboration with SA research
	Robotic surgery	Medium	Medium	Private sector deploying in some hospitals, room for expansion. Cost prohibitive for public sector.
	Teaching tools	High	Low	Potential market for robotic teaching aids, if enhance current teaching and/or mitigate staff shortages
	Automated delivery and dispensing	High	Medium	Significant opportunities in public sector. Some existing players in market

1.9 The report identifies some particularly promising opportunities, as well as possible market entry strategies that Dutch companies could pursue. These market entry strategies include direct exporting, licensing and franchising, partnering and joint ventures, buying a company and greenfield investment. Table 1 below combines these two components and suggests which market entry strategies would be most suitable for the specific opportunities identified.

Table 1: Market Entry Analysis

Sector	Subsector	Opportunity	Potential Buyers	Recommended Market Entry Strategies
Data Capture	Electronic Health Records	EHR software – private sector	Smaller hospital groups; primary care provider groups; GP and specialist practices	Direct exporting, Licensing and Franchising
		EHR software – public sector	NHI Fund	Direct exporting, Licensing and Franchising
	Routine Health Management Information	Advanced data analysis systems	Large private hospital groups	Direct exporting, Licensing and Franchising; Partnering and Joint Ventures
Communication and Knowledge Transfer	Telemedicine	Technology to enable virtual doctor-patient consultations	GPs and specialists; public sector; hospital groups	Direct exporting, Licensing and Franchising
	Virtual healthcare	Referral tools (between nurses/GPs and specialists)	GPs and specialists; public sector	Partnering and Joint Ventures, Buying a Company
		Multi-disciplinary team communication tools	GPs and specialists; public sector	Partnering and Joint Ventures, Buying a Company
		Technology to optimise patient journey	Medical aid schemes; public sector	Direct exporting, Partnering and Joint Ventures
Consumer Health Technologies	Consumer health informatics	Sleep tracking technology	Consumers (potentially subsidised by Vitality)	Direct exporting
		Meditation apps	Consumers (potentially subsidised by Vitality)	Direct exporting

Sector	Subsector	Opportunity	Potential Buyers	Recommended Market Entry Strategies	
Artificial Intelligence and Robotics	Wearables	Nutrition tracking technology	Consumers	Direct exporting, Licensing and Franchising	
		Wearable with fraud mitigation technology	Consumers (potentially subsidised by Vitality)	Direct exporting	
		Fraud mitigation technology	Wearable manufacturers	Direct exporting, Licensing and Franchising	
		Wearable with creative commercial offering to Vitality	Consumers (potentially subsidised by Vitality)	Direct exporting	
	Artificial Intelligence	Artificial Intelligence	Diagnosis and treatment decision support systems	GPs and specialists; facilities	Direct exporting, Licensing and Franchising
			Precision medicine	GPs and specialists; facilities (private sector)	Licensing and Franchising, Partnering and Joint Ventures
			DNA printing	GPs and specialists; facilities (private sector)	Licensing and Franchising, Partnering and Joint Ventures
		Robotics	Advanced imaging	GPs and specialists; facilities (private sector)	Partnering and Joint Ventures, Buying a Company
			Robotic and augmented reality teaching tools	Universities	Direct exporting, Demonstrations
			Automated delivery and dispensing	Public sector	Direct exporting, Licensing and Franchising

2. Introduction

- 2.1 FTI Consulting has been engaged by the Embassy of the Kingdom of the Netherlands to undertake a study of the health technology (“healthtech”) market in South Africa. The aim of the study is to help identify areas where Dutch and South African parties can collaborate to increase the uptake of healthtech solutions.
- 2.2 Health technology is the fourth component of health provision, along with health practitioners, facilities and pharmaceuticals. The term “health technology” encompasses both medical devices (from the relatively simple, such as syringes, to complex, high-tech devices, like magnetic resonance imaging (MRI) machines) and medical technologies (from basic software systems to cutting edge Artificial Intelligence (AI) and machine learning).
- 2.3 In this report we focus mostly on the latter, specifically the following four groupings:
- 1) Data capture technologies
 - a) Electronic health records (enabling sharing of patient data between points of care)
 - b) Routine health management information (e.g. web-based surveillance systems, electronic disease registers, electronic district health information systems)
 - c) Vital registration (the use of computerised systems for registration of death or births)
 - 2) Communication and knowledge transfer technologies
 - d) Health knowledge management (e.g. best practice guidelines managed and accessed electronically)
 - e) mHealth (e.g. use of mobile devices such as cell-phones to share information or to collect aggregate or patient data)
 - f) Telemedicine (e.g. use of ICT to provide care at a distance)
 - g) Virtual healthcare (e.g. teams of professionals working together via ICT)
 - 3) Consumer health technologies
 - h) Consumer health informatics (access to information on health by healthy individuals or patients)
 - i) Wearables
 - 4) Artificial Intelligence (AI) and robotics
- 2.4 As we explain in Section 3 below, healthcare provision in South Africa is split between what can be broadly characterised as a well-funded private sector and a resource-constrained public sector. Both sectors present potential markets for health technology products, with some overlap and some differences in the types

of technologies required in the two sectors.

- 2.5 In the sections which follow, we set out first more detail on the healthcare context in South Africa, followed by assessments of the markets for each of the identified subsectors of health technology. We then identify priority subsectors and suggest possible market entry strategies, before making some concluding remarks.

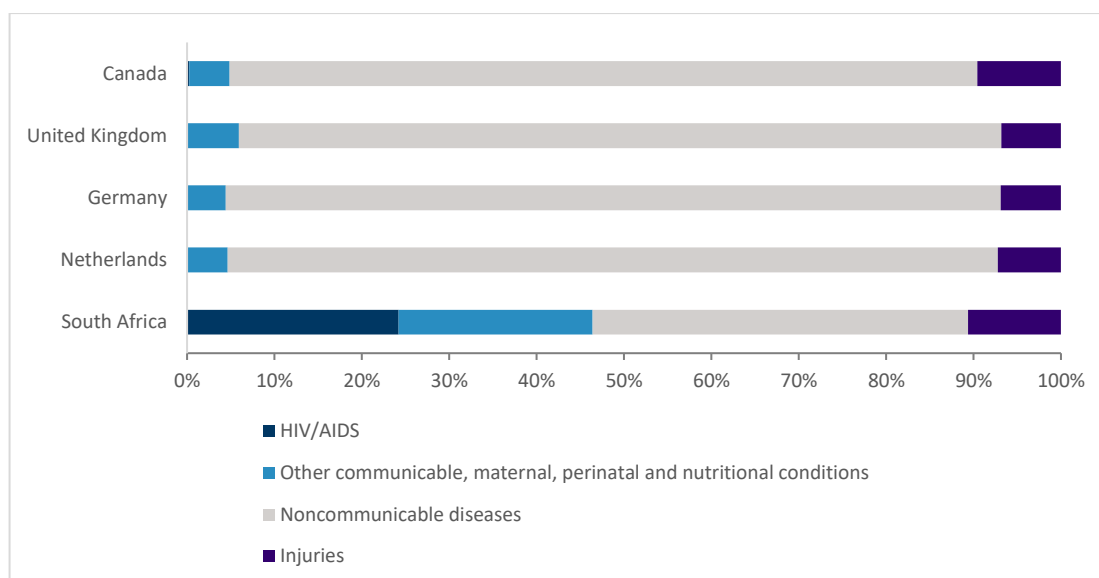
3. Context

- 3.1 In this section we introduce the healthcare market in South Africa, with more detail on the burden of disease, the structure of the healthcare system, the regulatory framework and potential future developments in healthcare policy.

South Africa's burden of disease

- 3.2 A country's burden of disease refers to the assessment of mortality, morbidity, injuries, disabilities and other risk factors specific to that country. South Africa is unusual in carrying a quadruple disease burden:
- i) Poor maternal, new-born and child health;
 - ii) Communicable diseases, including tuberculosis and HIV/AIDS, that are costly to treat;
 - iii) Prevalent non-communicable diseases; and
 - iv) High rates of violence and injury
- 3.3 Historically, a typical country's disease burden transitioned, as incomes grew, from one of infectious diseases, high child mortality and malnutrition to a predominance of degenerative, chronic diseases. Increasingly however, developing countries are experiencing a double burden, resulting from the simultaneous occurrence of communicable and non-communicable diseases. In the case of South Africa, there is the additional problem of high rates of trauma.
- 3.4 In Figure 2 below, we show that South Africa's disease burden is markedly different to high income countries, including the Netherlands. Specifically, an analysis of Disability-Adjusted Life Years (DALYs), a measure of the future stream of healthy years lost due to each incident of disease or injury, show that in South Africa, HIV/AIDS and other communicable diseases, including tuberculosis, and injuries make up a far larger proportion of the total disease burden than that of high-income countries. In absolute terms, South Africa has higher quantities of ill people per capita than other comparable countries, including the BRIC nations.

Figure 2: Disability-Adjusted Life-Years (DALYs) by Broad Group (2016)



Source: FTI Consulting calculations, World Health Organisation (2016) Disease Burden Estimates

South Africa's healthcare system

- 3.5 Healthcare in South Africa is provided through a highly unequal, two-tier system, with the private sector accounting for more than 50% of the country's total expenditure on healthcare, while providing care to just 16% of the population.³ This is due in part to the relatively high cost of private sector healthcare, high levels of income inequality in the country, and the limited number of individuals covered by medical aid (mutual health insurance).⁴ The public sector, which accounts for less than half of the country's total healthcare expenditure, services the remaining 84% of the population, a large proportion of which access fee-free primary care delivered through nurse-led clinics.
- 3.6 Generally speaking, the private, for-profit sector is well-resourced and caters to a population that tends to be wealthier, urban, and more likely to be formally employed. In contrast, the public sector caters to the majority of South Africans, and is challenged with fewer resources, both in terms of health professionals and equipment and infrastructure.
- 3.7 The numbers in Figure 3 below illustrate the different models of care in the public and private sectors. The public sector is dominated by a large number of public clinics and community health centres, and smaller numbers of hospitals of different sizes. In contrast, the private sector is dominated by acute hospitals, followed by day clinics and sub-acute facilities. Notably, private general practices are excluded from this comparison.⁵ However, it remains fair to say that the model of care in the private sector is acute-hospital centric, while healthcare provision in

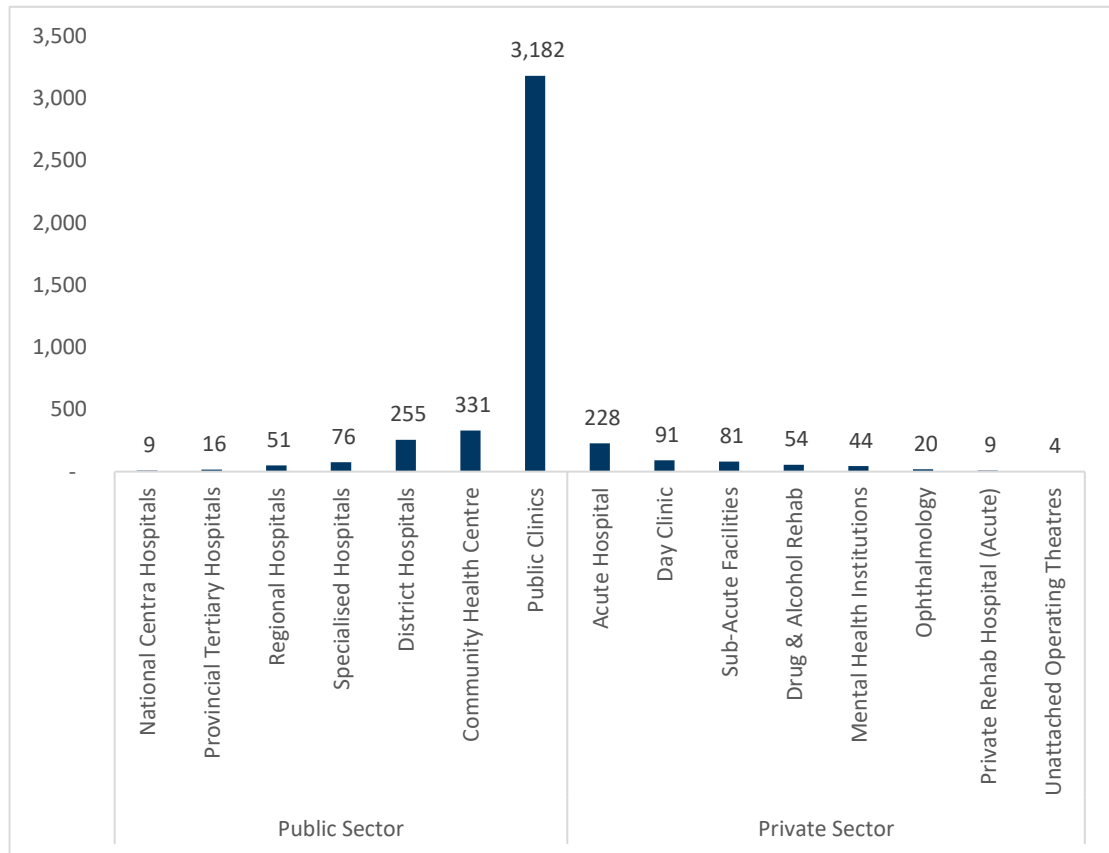
³ Ranchod et al. (2017). *South Africa's hospital sector: old divisions and new developments*. Accessible at https://www.hst.org.za/publications/South%20African%20Health%20Reviews/10_South%20Africas%20hospital%20sector_old%20divisions%20and%20new%20developments.pdf

⁴ Stats SA General Household Survey of 2018 found that 16.4% of the population were covered by medical aid in 2018.

⁵ No central database recording the number of GP practices exists.

the public sector is centred around primary care facilities.

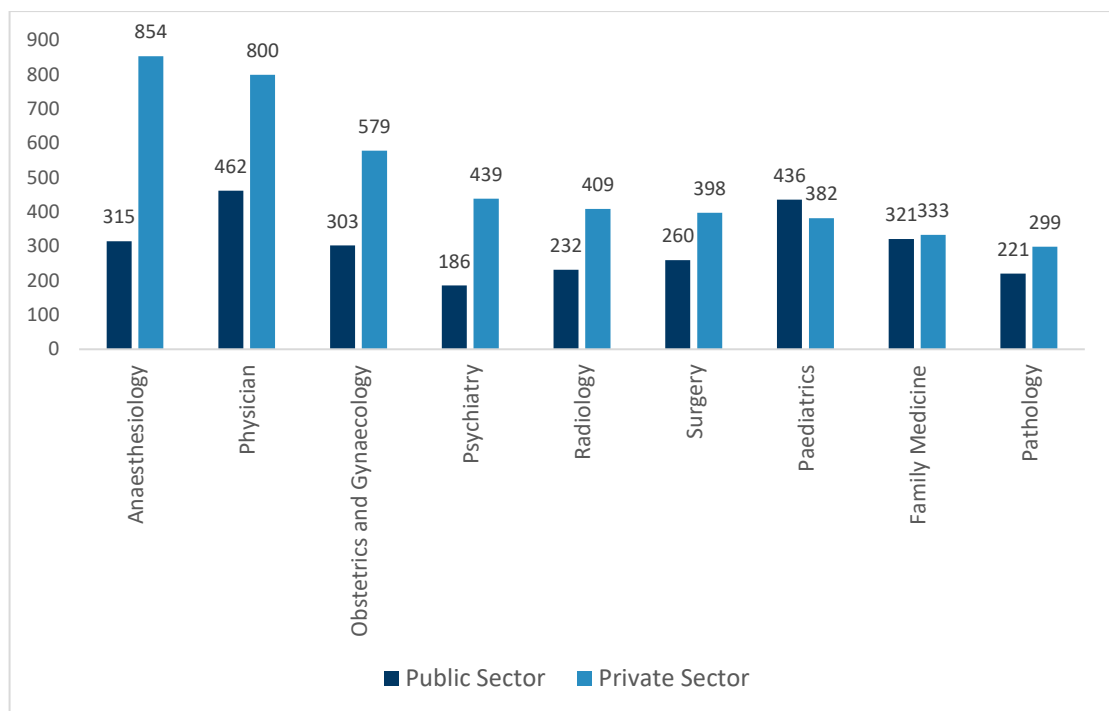
Figure 3: Distribution of public and private healthcare facilities by type



Source: South African Health Review (2017) Public Sector Facilities, Econex (2017) The Economic Footprint of Private Hospital Groups in South Africa

3.8 Shortages of health professionals are much more pronounced in the public sector than the private sector. For example, recent data, illustrated in Figure 3 below, suggest that in eight of nine branches of medicine, the private sector has more specialists than the public sector, despite providing care to less than 20% of the population of the country. Only in paediatrics does the public sector have more specialists.

Figure 4: Distribution of specialists by public and private sector

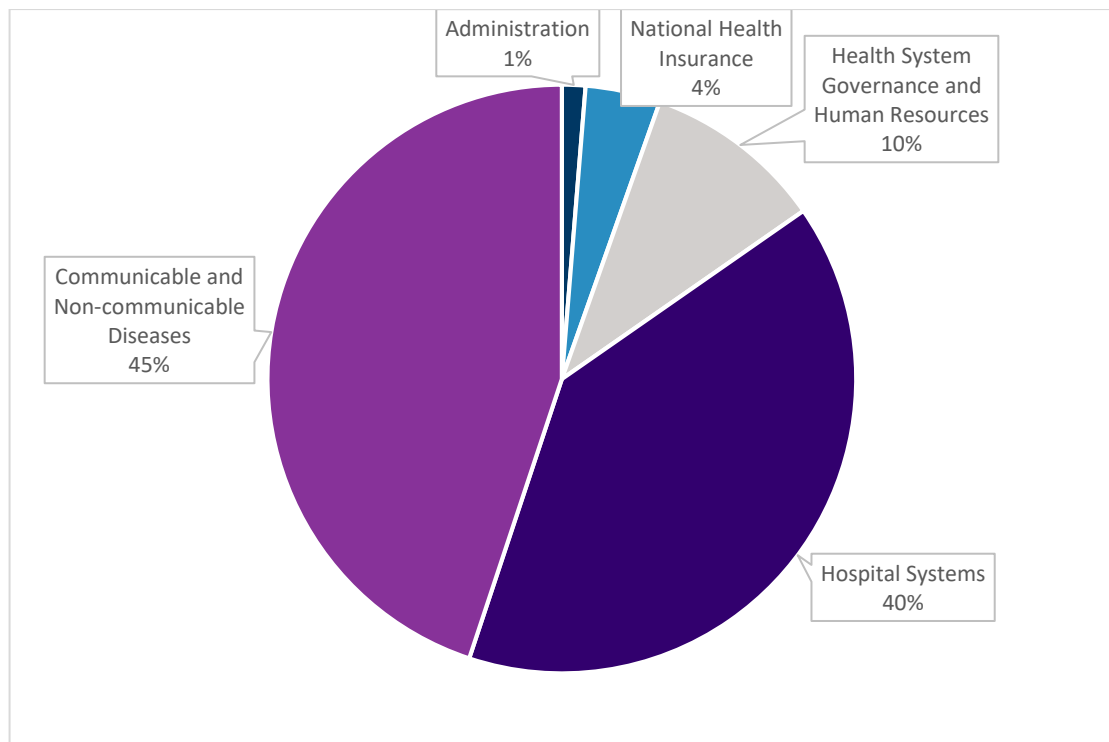


Source; Adapted from Wishnia, J., Strugnell, D., Smith, A. M. & Ranchod, S. (2019). *The supply of and need for medical specialists in South Africa*. Cape Town: Percept.

Public sector healthcare

3.9 R 51bn (3.19bn euros) was allocated to public sector health expenditure in the 2019/2020 budget. Hospital systems and health facility infrastructure management are the second and third largest expenditure subcategories in the budget, after HIV, AIDS and STI care. The National Department of Health (NDoH) has allocated R 984m (62m euros) to investment in hospital facilities infrastructure management at a national level, and R 6bn (380m euros) towards hospital facilities infrastructure management to be executed by the provincial departments of health. Figure 5, below, shows the composition of the NDoH budget.

Figure 5: National Department of Health Budget 2019-2020

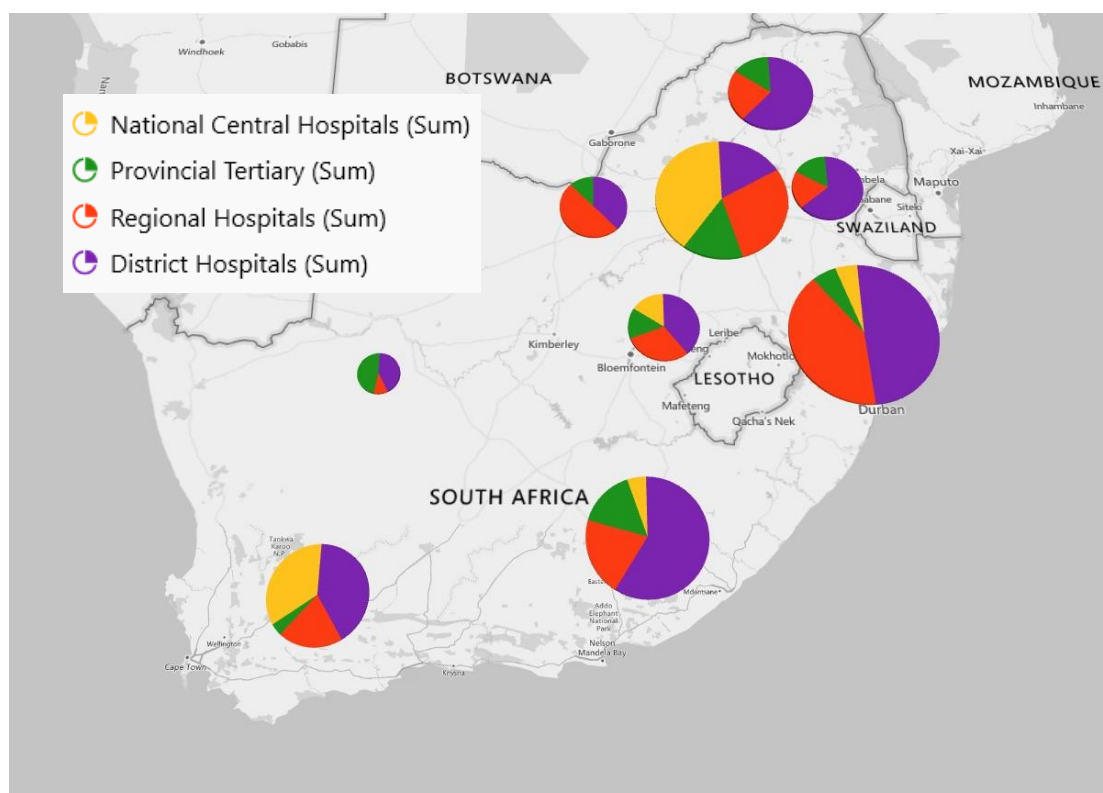


Source: National Department of Health Budget, accessible at www.doh.gov.za

Note: Percentage per item show is percentage of total NDoH budget.

3.10 In terms of hospital distribution, public sector facilities are generally distributed according to population. In the provinces with more urban populations (Gauteng and the Western Cape), the share of national central hospital beds is higher, while in populous rural provinces (KwaZulu Natal), the share of regional and district hospital beds is higher. Figure 6 below shows the distribution of public sector hospital beds by type.

Figure 6: Public hospital distribution by province and type (2015)



Source: Day and Gray (2016). *Health and Related Indicators in South African Health Review*. Accessible at: <https://www.hst.org.za/publications/South%20African%20Health%20Reviews/SAHR%202016.pdf>
 Note: The share shown in the pie chart is by the number of beds registered by hospital type in 2015.

Private sector healthcare

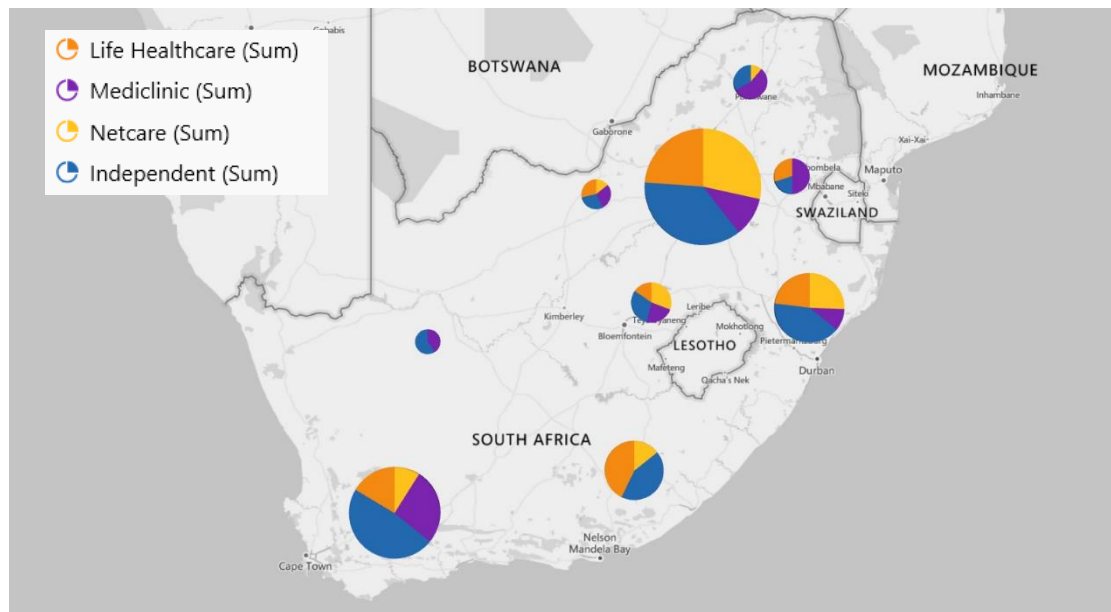
- 3.11 The vast majority of activity in the private sector is funded by medical aid schemes, which are not-for-profit mutual organisations in which members' funds (and risks) are pooled. There are currently around 80 medical schemes in South Africa; some of these undertake their own administration (for example, the assessment and payment of claims, and care management, e.g. pre-authorisation of claims, chronic disease management programmes), while others outsource these tasks to for-profit, administration companies. The largest medical scheme in South Africa, Discovery Health Medical Scheme (DHMS) outsources its administration to Discovery Health (Pty) Ltd, which also provides administration services to other medical schemes in addition to DHMS.
- 3.12 Approximately 81% of private healthcare expenditure is funded from private medical schemes, while 14% is paid for by out-of-pocket contributions⁶. The remainder is funded by charitable donations and other sources of institutional funding. It is therefore important to consider whether the cost of health technologies will be reimbursed by the schemes, as this will certainly impact uptake.
- 3.13 On the provider side, there are three main private hospital companies in South Africa (Netcare, Mediclinic and Life Healthcare) as well as a grouping of

⁶ Council for Medical Scheme's Annual Report. 2018. Accessible at https://www.medicalschemes.com/files/Annual%20Reports/CMSAR2018_19.pdf

independent hospitals called the National Hospital Network (NHN). The large hospital groups are important purchasers of health technology in South Africa, given both their national footprints and available resources to adopt innovative, high-value health technologies. However, the three hospital groups have recently come under fire, for example, during the recent Health Market Inquiry, for perceived market dominance and they are reportedly struggling to obtain licences for new hospitals. This may spur the growth of smaller hospital groups (like Lenmed) and independent hospitals.

3.14 Figure 7 below shows the distribution of hospital beds by province of the major hospital groups.

Figure 7: Private Hospital Bed Distribution by Province and Group (2017)



Source: Econex (2017) *The Economic Footprint of Private Hospital Groups in South Africa*
 Note: The share shown in the pie chart is by the number of beds registered per hospital group in 2017.

Regulatory framework

3.15 The regulatory environment shapes business practices in every sector of the economy. As in other countries, healthcare, and health technology, in South Africa are subject to high levels of regulation and intervention. We outline the key regulatory bodies and legislation below.

Regulatory bodies and pertinent acts

3.16 In South Africa, the National Health Act (61 of 2003), including the amendment dealing with core standards, regulates both private and public healthcare providers, with the stated aim of encouraging the best health services that available resources can afford, emphasising the need for cost-effective health technologies.

3.17 The Medicines and Related Substances Control Act (101 of 1965), as amended, regulates the sale and distribution of medicines, as well as medical devices and technologies, which are broadly defined in the Act to include simple and complex

devices.

- 3.18 The Health Professions Council of South Africa (HPCSA) is the statutory body tasked with protecting the public and guiding professionals. Many of the HPCSA guidelines have come in for criticism recently, most notably by the Health Market Inquiry, in regard to restrictions on fee sharing, multidisciplinary group practices, and the employment of doctors. The HMI concluded the HPCSA's guidelines in these areas have significantly inhibited the evolution of innovative and integrated models of care.
- 3.19 The Medical Schemes Act (131 of 1998) regulates the way in which schemes operate, the value of reserves schemes should hold, and the cover provided by schemes, including setting Prescribed Minimum Benefits (PMBs), the set of diagnosis-treatment combinations that must be reimbursed by schemes. The Medical Schemes Amendment Bill introduced in June 2018 seeks to fundamentally alter the role of schemes in light of the government's plans for a National Health Insurance (NHI) programme. This is dealt with in more depth in the discussion of NHI in the next subsection.
- 3.20 The Council for Medical Schemes (CMS) provides regulatory supervision for private health financing schemes and reports annually on scheme expenditure and other metrics. The Council's mandate includes protecting and informing the public in respect of medical schemes, making sure that complaints are handled appropriately, ensuring compliance with the Medical Schemes Act and improving the management and governance of medical schemes.
- 3.21 The Protection of Personal Information (POPI) Act (4 of 2013) regulates the protection of personal information that is processed both by private and public bodies. The Act sets up minimum requirements with which businesses must comply when processing personal information. It is similar to the European Union's General Data Protection Regulation (GDPR). Given the highly sensitive nature of health data, there are specific protections that relate to biometric data.
- 3.22 Broad-Based Black Economic Empowerment (B-BBEE) is a legislative framework the primary purpose of which is to address the legacy of apartheid and promote the economic participation of previously disadvantaged groups in the South African economy.⁷ All firms wishing to supply products or services to the public sector must consider B-BBEE certification. Further, recent amendments to the B-BBEE scorecard incentivise businesses to use suppliers that are B-BBEE compliant, making B-BBEE an important consideration even for firms supplying only to private sector clients.
- 3.23 Many multinationals establish a South African operation which complies with B-BBEE requirements. Alternatively, there are specific carveouts for multinationals in the B-BBEE Codes of Good Practice that take into consideration that multinationals may have global policies preventing them from complying with certain aspects of the B-BBEE codes. The specifics of B-BBEE are laid out in detail in Annex 2: Broad-Based Black Economic Empowerment.
- 3.24 Prior to 2015, South Africa had no specific regulations for health technology,

⁷ Werksmans Attorneys. (2018). B-BBEE Act and Codes Explained. Retrieved from <https://www.werksmans.com/wp-content/uploads/2018/11/BBBEE-Codes-Explained.pdf>

barring electronic medical devices which were regulated by the Medicines Control Council (MCC) under the Medicines and Related Substances Control Act (discussed above). The passing into law of the Medicines and Related Substances Amendment Act 14 of 2015 introduced a new, more complete, regulatory regime into the sector.

- 3.25 Most significantly, the amendment established the South African Health Products Regulatory Authority (SAHPRA), whose mandate was expanded from that of the Medicines Control Council (MCC) which preceded it. The legislation now requires that all medical devices and technologies (not only electronic products) are registered and regulated prior to sale in the local market. All technologies, from syringes to software, must now be distributed by a licensed provider, and demonstrate their compliance with the “Essential Principles” laid out by SAHPRA. This is dealt with in more depth in Annex 1: Regulation of medical devices and technologies, but it is important to note that one of the ways in which compliance with the Essential Principles can be demonstrated is international accreditation by a medical device certification body, for example, CE or FDA certification.

Future policy developments in South African healthcare

- 3.26 The healthcare sector in South Africa is currently in a state of flux, with several processes in train that may result in huge structural changes to the sector. Between 2014-2019, the Competition Commission of South Africa undertook an inquiry into the private healthcare sector. The Health Market Inquiry (HMI) made a number of recommendations which will have implications for the operation of the private healthcare sector. Meanwhile, the government’s proposed National Health Insurance (NHI) programme will fundamentally alter the way both the public and private sector operate. We briefly consider these potential changes and their implications for the health technology sector in the subsections below.

Health Market Inquiry

- 3.27 In the private sector, the Health Market Inquiry (HMI) released its Final Findings and Recommendations Report in September 2019.⁸ These cover a range of areas, with recommendations relating to facilities, practitioners and funders. Most significantly, the report proposes the creation of a Supply Side Regulator for Health (SSRH) with four main functions: healthcare facility planning (including licensing); economic value assessments; health services monitoring; and health services pricing.
- 3.28 With respect to technology, the HMI recommends more formal assessments of the benefits and economic value of health technology. Relevant extracts from the report include:

- i) *“We attribute the increase in expenditure on medical devices to the lack of appropriate health technology assessments in South Africa... the absence of regulations on HTA [health technology assessments] is a significant*

⁸ Competition Commission of South Africa (2019) *Health Market Inquiry Final Findings and Recommendations Report*. Available : <http://www.compcom.co.za/wp-content/uploads/2014/09/Health-Market-Inquiry-Report.pdf>

regulatory failure.”⁹

- ii) *“A critical tool of supply-side regulation is a system of assessing the cost effectiveness of health technology and interventions across the entire health system. We have not been provided with evidence of publicly available cost-effective standards of care and treatment protocols being used across the healthcare sector. The absence of this information makes it difficult to assess the appropriateness of certain courses of treatment and to evaluate quality of care and value for money.*

To inform practice and to curb waste on procedures, equipment and medicines that are not beneficial, and may not be cost effective, the SSRH should have a Health Technology Assessment (HTA) function to produce guidelines for both the private and public sector, though these may differ.”¹⁰

- 3.29 The HMI further recommends the development, based on standard accepted approaches, of standards of care, evidence-based treatment protocols, and processes for conducting HTAs to assess the impact, efficacy and costs of medical technology, medicines and devices, relative to clinical outcomes. Where appropriate, this should be done in collaboration with representatives of patients, academia, regulators, such as SAHPRA and the Council for Medical Schemes, and national and international experts.¹¹

National Health Insurance

- 3.30 The National Health Insurance (NHI) Bill was published in August 2019 and, if and when implemented, will bring about significant change in the way healthcare is provided in South Africa. The Bill envisions a single national health system where the NHI Fund becomes the single buyer of healthcare products and services (from both public and private sector providers).
- 3.31 The most controversial aspect of the Bill is Section 33, which limits the role of medical schemes, restricting them to offering ‘complementary cover to services not reimbursable by the Fund’. The interpretation of this clause continues to be widely debated, but if strictly interpreted, it would mean the end of medical schemes in their current form, with potentially serious implications for private sector providers as well if private sector funding was not replaced by NHI funding.
- 3.32 The Bill also provides for the creation of an Office of Health Products Procurement, which will be responsible for, among other things, the procurement of health technology and equipment on behalf of the fund. The Bill states the following:

⁹ HMI Final Findings and Recommendations Report, chapter 4, paragraph 188.

¹⁰ HMI Final Findings and Recommendations Report, chapter 9, paragraphs 101-102.

¹¹ HMI Final Findings and Recommendations Report, chapter 9, paragraph 103.

“The Office of Health Products Procurement must –

- (a) determine the selection of health-related products to be procured;*
- (b) develop a national health products list;*
- (c) coordinate the supply chain management process and price negotiations for health-related products contained in the list mentioned in paragraph (b);*
- (d) facilitate the cost effective, equitable and appropriate public procurement of health-related products of behalf of users;*
- (e) support the processes of ordering and distribution of health-related products nationally, and at the district level with the assistance of the District Health Management Office;*
- (f) support the District Health Management Office in concluding and managing contracts with suppliers and vendors;*
- (g) establish mechanisms to monitor and evaluate the risks inherent in the public procurement process;*
- (h) facilitate the procurement of high cost devices and equipment; and*
- (i) advise the Board on any matter pertinent to the procurement of health-related products.”¹²*

- 3.33 While private sector providers are envisaged to remain in operation (providing services to the NHI Fund), the public sector would become a more significant buyer of medical technologies, through the Office of Health Products Procurement. This would increase the importance of B-BBEE compliance for health technology suppliers.
- 3.34 Depending on the level of funding made available to the NHI Fund and the speed and success of implementation, NHI may result in growth in the health technology market in South Africa. At this stage, however, there is still much uncertainty surrounding the detail of what NHI will look like, and whether the plans will ever be put into practice. In any event, implementation is likely to be slow and both the public and private sectors will continue to operate largely as they do now for at least the next five years. That said, providers of all healthcare products and services should be starting to think about how to position themselves as suppliers to the NHI Fund, as part of their medium-term strategy.

¹² National Health Insurance Bill, Section 38(3).

4. Health technology sector overview

- 4.1 Globally, the healthcare sector is thought to lag behind other industries in its use of technology by at least 10 years¹³, while South Africa is also behind the curve in terms of technology adoption more generally¹⁴. These facts combined suggest that the South African healthcare technology market presents significant opportunities for growth.

Current market

- 4.2 The current market for medical technology in South Africa is still dominated by 'traditional' devices, while this report focuses on more sophisticated, high tech products and solutions. However, the information below provides useful context on the current buying patterns of South African users of health technology.
- 4.3 It is estimated that 90% of the medical technology currently used in South Africa is imported.¹⁵ Combining this figure with import data suggests a total market of around R 350 billion (22 bn euros) in 2018. The value of imports reached R 317 billion (19.7 bn euros) in 2018, compared to R 2.67 billion (166 m euros) of exports¹⁶. Note that these figures refer to merchandise trade statistics and therefore do not include services or software, which comprise an increasingly important proportion of health technology. As such, the market for health technology in its broadest sense in South Africa can be estimated to be significantly in excess of R 350 billion (22 bn euros).
- 4.4 As shown in Figure 8 below, the majority of medical devices and technology is imported from the United States, which supplied 28% of total imports over the last 10 years. Following the United States are Germany and China, with 14% and 9% respectively of total imports from 2010 to mid-2019. Other import partners include Switzerland, the United Kingdom and Japan.
- 4.5 Notably, the Netherlands supplied 3% of total medical devices and technology during this time period, highlighted in orange in Figure 8 below. In 2018, the value of medical technology imported from the Netherlands was R 390 m (24.9 m euros). This is nearly double the R 199 m (12.3 m euros) imported from the Netherlands in 2012.

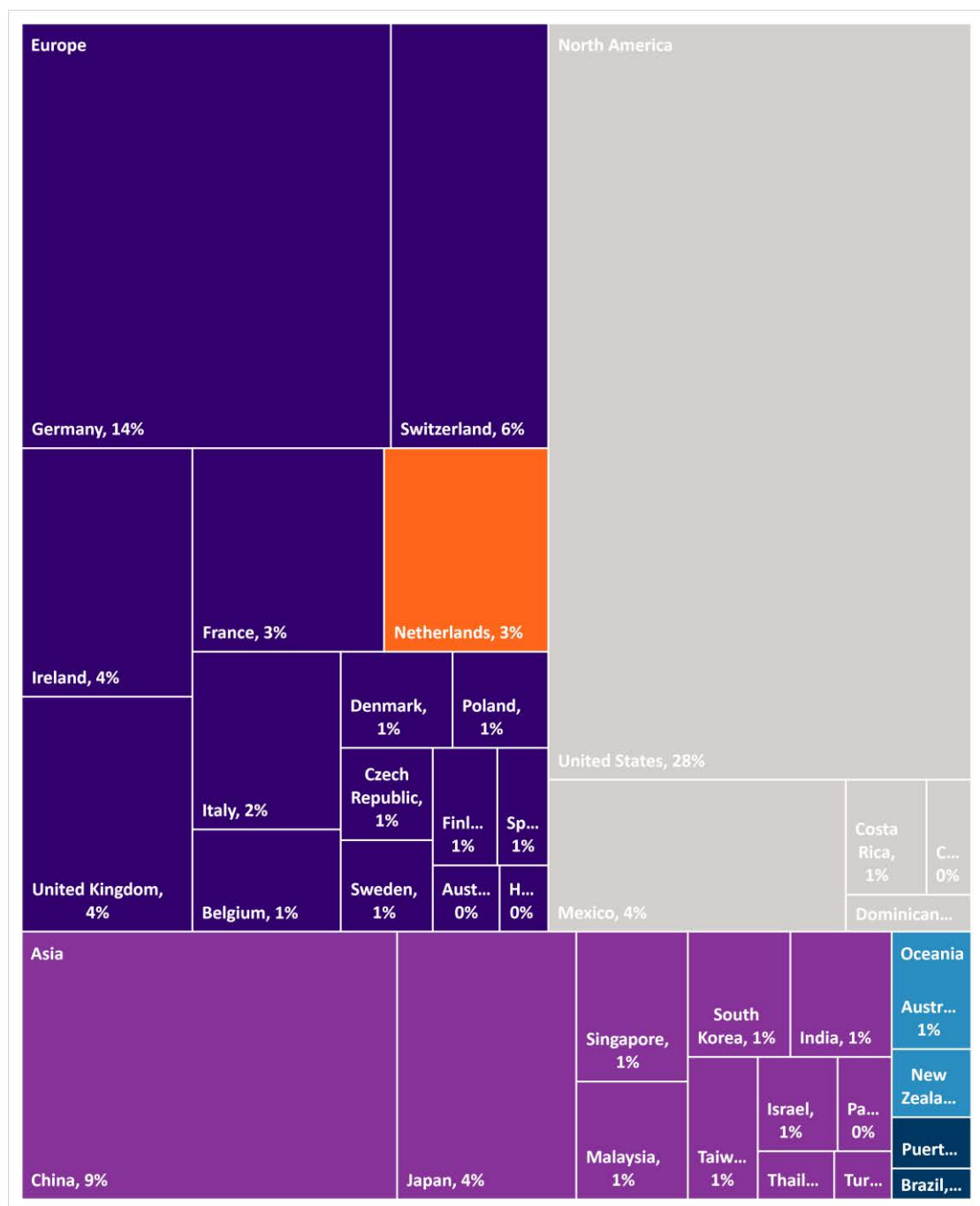
¹³ Nuffield Trust (2016). *Delivering the benefits of digital health care*, Accessible at <https://www.nuffieldtrust.org.uk/files/2017-01/delivering-the-benefits-of-digital-technology-summary-web-final.pdf>

¹⁴ Goldstuck, A (2019). *Fourth Industrial Revolution in South Africa*. Accessible at <http://www.worldwideworx.com/wp-content/uploads/2019/07/Exec-Summary-4IR-in-SA-2019.pdf>

¹⁵ Sudesh Sivarasu, Associate Professor of Biomedical Engineering at the University of Cape Town, <https://www.news.uct.ac.za/article/-2019-09-11-health-tech-appropriate-over-affordable>

¹⁶ Most exports were to neighbouring countries.

Figure 8: Origins of South African Imports of Medical Devices and Technology

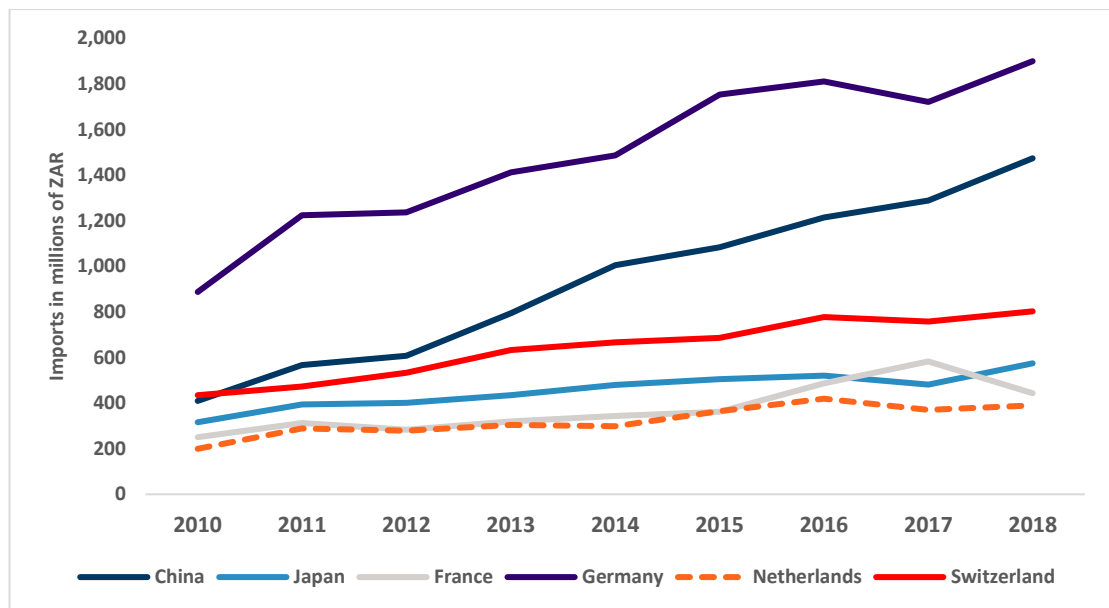


Source: FTI Calculations based on SARS Merchandise Trade Statistics.

Note: Data included from 2010 to May 2019. HS codes included for medical devices and technologies specified under Chapter 90 of the SARS Tariff Book.

4.6 In terms of import growth, Germany and China are two of the fastest growing sources of imports, as illustrated in Figure 9 below. Imports from the Netherlands have grown at a rate similar to that of Japan and France.

Figure 9: Imports of Medical Technology and Devices 2010-2018

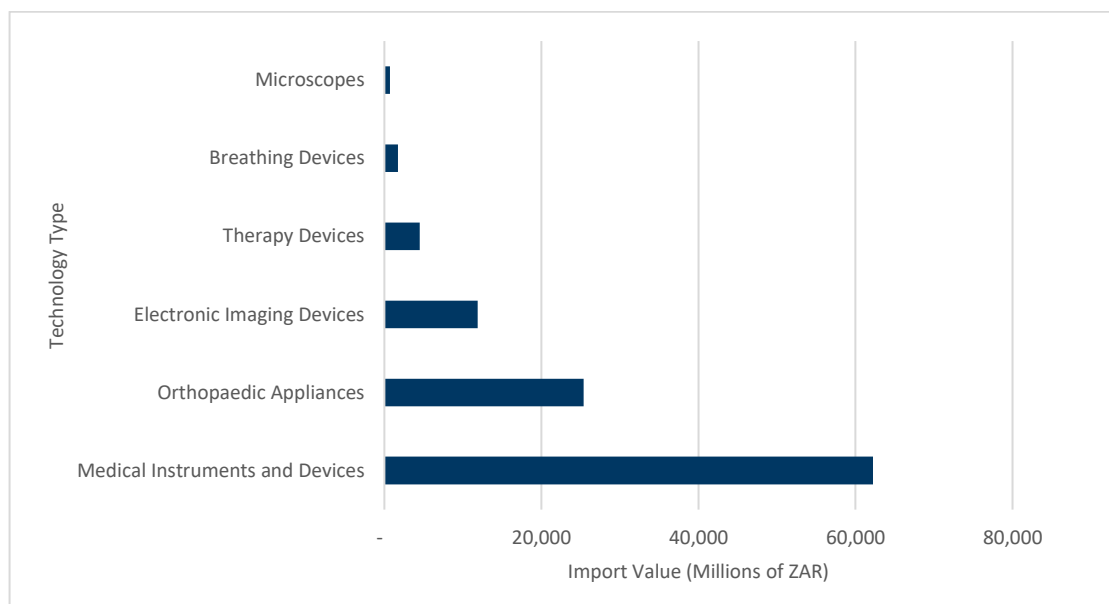


Source: FTI Calculations based on SARS Merchandise Trade Statistics.

Note: Data included from 2010 to May 2019. HS codes included for medical devices and technology specified under Chapter 90 of the SARS Tariff Book.

4.7 In South Africa, a broad range of health technologies are used, both in the private and public sector. Figure 10 below presents the breakdown of imports of medical technology between 2010 and 2019 by type: medical instruments and devices, electronic imaging devices, orthopaedic appliances, therapy devices and microscopes.

Figure 10: Imports into South Africa of medical technology 2010-2019



Source: FTI Calculations, SARS Merchandise Trade Statistics

4.8 Local production of medical devices is primarily in low-tech consumables, including bandages, dressings, needles and catheters.

Barriers to greater implementation of health technology

4.9 We have identified five major barriers to greater use of technology in healthcare provision, which we set out below. These present more or less significant challenges, depending on the specific subsector in question (we explore these differences in the analysis in Sections 5, 6, 7 and 8 below).

- **Regulatory constraints:** The regulatory environment presents a consistent challenge across the industry, but different regulations and regulatory bodies are relevant in different subsectors. For example, the Health Professions Council South Africa (HPCSA) ethical rules for members have played a large role in preventing the expansion of telemedicine, while in the medical devices space, the certification backlog at the South African Health Products Regulatory Authority (SAHPRA) is the most significant issue.
- **User resistance:** The success of many technologies depends on levels of adoption by either health professionals or patients/consumers, or in many cases both. Reluctance to move to new ways of doing things is a serious problem among many health professionals.
- **Financing constraints:** The implementation of new technology often involves very substantial financial investments, with resulting cost savings often only being realised some time down the line. In today's difficult economic environment, lack of available financing acts as a constraint in both the public and private sectors.
- **Lack of appropriate solutions:** Many interviewees reported struggling to find technologies that were able to meet their particular needs, or were appropriate to the specific South African context.
- **Bureaucratic decision making:** Protracted decision-making processes are an issue in both the public and private sector in South Africa. This can make the sales cycle for new products very long, especially when the required financial investment is large, or the innovative nature of the product means that the resulting benefits are uncertain.

Future trends

4.10 However, while the obstacles are significant, there are also strong dynamics at play that will drive growth in the health technology market globally and in South Africa. We have identified three key trends that will create demand for health technology going forward:

- **Consumerisation of healthcare:** While conservative cultures may mean that disruptive change will not be initiated proactively by providers, providers will come under pressure from consumers/patients to act. One interviewee quoted a US study reporting that 65% of millennials will not engage with a healthcare provider unless they can book an appointment online. There are huge opportunities in the market for technology which connects consumers/patients and providers.

- **Pressure to reduce costs:** There is intense pressure to reduce costs across both the public and private sectors. The potentially huge financial returns available to technology companies that enable healthcare providers to reduce cost have attracted big investors into the healthcare space, e.g. Warren Buffett/Jeff Bezos (amazon.care).
- **Increased focus on outcomes:** There is growing recognition that healthcare purchasing must become more value-based, with a much stronger focus on the outcomes of healthcare delivery. The resulting need for technologies which enable outcomes measurement and facilitate more integrated care across pathways will be another significant driver of growth.

4.11 While these trends will drive demand, many of the companies we interviewed, particularly in the healthcare administration sector, reported that they rarely buy software off the shelf and prefer to build their own solutions in-house. Underlying this preference for bespoke software was a sense that the South African market has specific characteristics that require tailored technology.

4.12 NHI will clearly be another key dynamic in the South African market and its introduction will create significant opportunities (as well as threats). These opportunities will be seized by companies which are able to scale up to meet the challenge of delivering on a national footprint (and who are able to prove they can scale up). Nicholas Crisp, who has responsibility for setting up the NHI Fund, has emphasised the need for evidence that solutions can work at scale. Firms will need to demonstrate that they have a model that is already working in the country; many companies are trying to do this at the moment so that they are well positioned to bid for NHI contracts when the time comes.

Structure of the next sections

4.13 As discussed in the introduction, we have structured our analysis around four broad groupings of health technologies: data capture technologies; communication and knowledge transfer technologies; consumer health technologies; and Artificial Intelligence and robotics. In the sections that follow, we address each of these groupings in turn, focusing specifically on growth drivers and barriers, highlighting the key players both in terms of purchasers and manufacturers, estimating the size of the market (where information is available), and identifying the most promising opportunities in the grouped sub-sectors.

4.14 This analysis is based on both desk-based research and interviews with key players in healthcare and health technology in the private and public sectors, as well as research institutes and academia.

5. Data capture technologies

- 5.1 For the purposes of this report, data capture technologies include Electronic Health Records (EHRs), routine health management information systems, and vital registration.
- 5.2 Electronic Health Record (EHR) systems, which capture patient health data electronically and enable the sharing of that data between different points of care, are a pre-requisite for more sophisticated routine health management information (RHMI) systems. These are defined as technologies that provide information at regular intervals of a year or less to meet predictable information needs, for example, web-based surveillance systems, electronic disease registers and facility- and district-level management information systems. RHMI systems are increasingly seen as an essential component of efficient, country-owned, integrated national systems.¹⁷

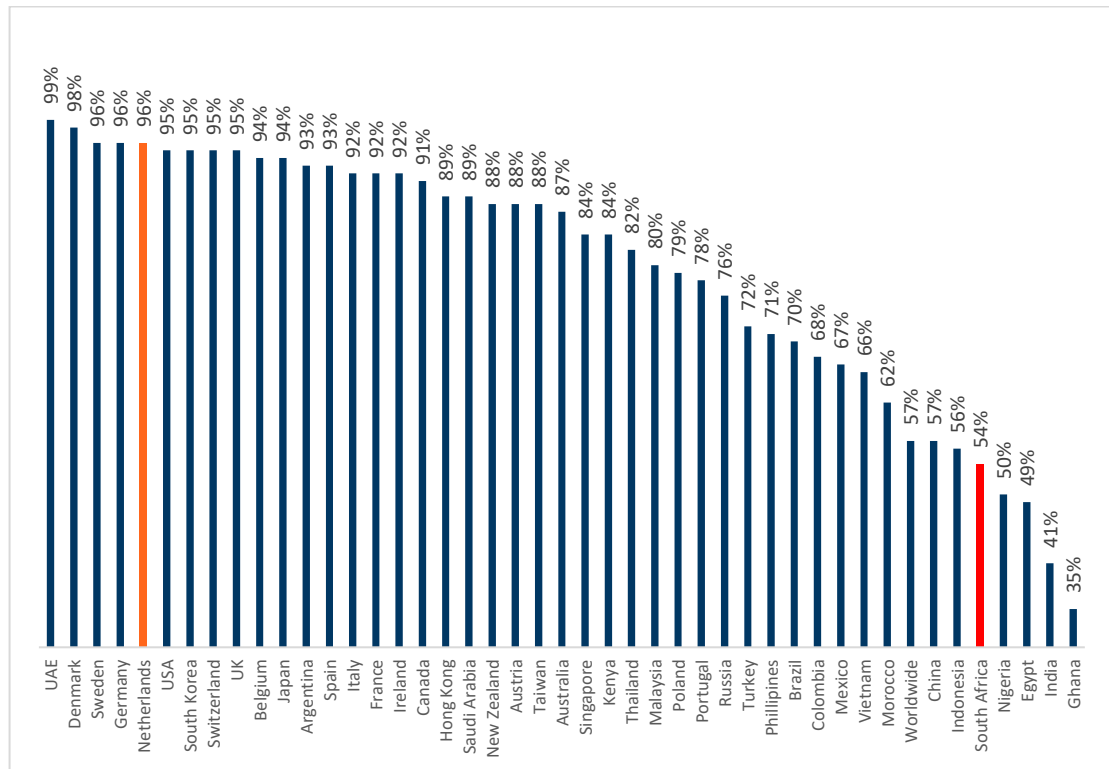
Growth drivers and barriers

- 5.3 The market for Electronic Health Record (EHR) systems, also sometimes called Electronic Medical Record (EMR) systems, in South Africa is potentially very large (we discuss some estimates in later subsections). The benefits of electronic data capture, and the pressing need to move away from paper-based systems, have been acknowledged across both the public and private sectors for some time, and there has already been a fair amount of activity in the EHR market. In the private sector, a number of private hospital groups are trialling technologies or rolling out programmes, while the public sector has been pursuing a national EHR strategy since at least 2012 (when the eHealth Strategy South Africa was published) and have reportedly already spent R 4bn (252m euros). However, there have been a number of barriers to implementation, which we discuss below.
- 5.4 In the private sector, the biggest stumbling block has been interoperability (between different providers (facilities and professionals) and between providers and funders). This has also been an issue in the public sector, for example, between different provinces. The implementation of the eHealth Normative Standards Framework for Interoperability in 2012 was a major step towards the possibility of a national EHR system and the flow of information between institutions. However, uptake of the standards remains an issue. To address this, CSIR is in the process of setting up a lab to certify compliance of EHR systems with the interoperability standards framework, on behalf of the National Department of Health.
- 5.5 In the public sector, the lack of underlying infrastructure continues to be the most significant constraint, and more than half of South African public health centres continue to use a paper-based record system. Internet connectivity, particularly in rural areas, is the biggest challenge, but in some places, there is a lack of even basic infrastructure, such as electricity. The connectivity issue is illustrated in Figure 11 below, which highlights internet penetration rates in the Netherlands, South Africa

¹⁷ Hotchkiss DR1, Diana ML, Foreit KG, (2012). *How can routine health information systems improve health systems functioning in low- and middle-income countries? Assessing the evidence base*. Accessible at <https://www.ncbi.nlm.nih.gov/pubmed/22894044>

and other comparator countries.

Figure 11: Internet Penetration by Country (2019)



Source: Hootsuite We Are Social's Digital 2019 Report

- 5.6 While the lack of reliable, high-speed internet connectivity is widely acknowledged to be a serious problem in the delivery of healthcare services, broadband rollout is not the responsibility of the National Department of Health and sits elsewhere within national and provincial government.
- 5.7 In addition to connectivity, the public sector, and to a lesser extent the private sector, also struggle with skill levels among staff in the use or integration of ICT. This is a problem across the public sector and can lead to purchased technology sitting idle; one interviewee quoted the example of biometric technology at airports not being used because it was slowing down the queue. It was also reported that MomConnect (an SMS-based technology discussed in Section 6 below) was developed under a PPP arrangement but is still being privately run because the government doesn't have the staff to take it over. Greater use of electronic data systems will therefore require investment in ICT literacy training, as well as infrastructure.
- 5.8 There is a fairly unanimous view from players across both the public and private sectors that routine health management information technologies are only likely to be widely adopted once the underlying ICT infrastructure and integrated EHR systems are in place.
- 5.9 A centralised, electronic system records births, marriages and deaths through the civil registrar's office. According to Statistics South Africa, the national statistical service, birth registration completeness was estimated at 89% in 2018, the most

recent year for which information is available.¹⁸

Key players

5.10 As discussed above, both the public and private sectors in South Africa present potential markets for EHR and RHMI systems. We introduce the major players in the two sectors in turn.

Private sector

5.11 The three large hospital groups (Life Healthcare, Netcare and Mediclinic), which together constitute 66% of the private hospital sector¹⁹, are the largest potential purchasers of EHR technologies, although, as we discuss in the next subsection, they are at different stages of the EHR procurement process.

5.12 Other players in the hospital market include National Hospital Network (NHN), a network of private hospitals that has been granted permission to collectively bargain and procure goods and services, and represents 25% of the private hospital beds in South Africa. There are also other smaller hospital groups including Lenmed Health and Clinix Health Group.

5.13 The larger administrators (Discovery, MMI, Medscheme and Universal) would also theoretically present possible markets for EHR and RHMI programmes, as they have, or aspire to have, their own systems which they require health professionals and facilities to use or connect with. However, many of these companies, for example, Discovery Health and Universal Healthcare, have chosen to build their own software in-house.

5.14 A number of established global technology companies are active in the South African market, including Philips, GE, Altron (and their subsidiary Med-e-Mass), Accenture and EOH.

Public sector

5.15 Currently the major buyers of EHR systems in the public sector are the provincial departments of health, with different EHR systems provided by different vendors in the various provinces and limited interoperability between these systems.

5.16 The Free State Department of Health uses Meditech's Expanse EHR, a web-based platform that is interoperable according to the eHealth Normative Standards Framework for Interoperability and includes billing information and patient data. In parts of the Eastern and Western Cape, public hospitals utilise the UniCare administration and record keeping system, a text-based database made by South African firm Delta 9 Healthcare Administration, that works well on older ICT hardware. In the Western Cape, Clinicom and AR billing systems are used in 49 hospitals, centralising patient data, making patient history available to doctors across the province and improving outpatient management.

5.17 Going forward however, when the government's plans for NHI are implemented,

¹⁸ Statistics South Africa (2018) *Recorded live births*. Accessible at: <http://www.statssa.gov.za/publications/P0305/P03052017.pdf>

¹⁹ By bed numbers. Bed data sourced from Econex (2017) *The Economic Footprint of Private Hospital Groups in South Africa*.

the NHI Fund will be the major public sector purchaser. In fact, we understand that responsibility for the government's National eHealth Strategy has already transferred from the Department of Health to the NHI Fund.

- 5.18 The Department of Home Affairs manages vital registration in South Africa.

Estimated size of the market and potential opportunities

- 5.19 Anecdotal estimates put the global market for care coordination software (including EHRs) at around US\$17 billion, with an average annual growth rate in recent years of 15%.
- 5.20 According to the Philips Future Health Index of 2017, which focuses on access to, satisfaction with, and efficiency of healthcare systems across 16 countries, the size of the market for electronic health records in South Africa was:
- R 446m (28m euros) for Electronic Health Records in Hospitals; and
 - R 376m (24m euros) for Electronic Health Records for ambulatory services.
- 5.21 In both categories, the size of the SA market was about one tenth of the average for the 16 countries included in the study.²⁰
- 5.22 Medical aid schemes held R 66bn (4.16bn euros) in reserves in 2018, which gives some sense of their buying power for big investments, such as technology systems. We also understand that the bigger players in the administration market are spending between five to eight percent of turnover on technology spend. If this percentage is applied to total medical scheme administration expenditure, as reported by the Council for Medical Schemes, technology spend is estimated to be between R 656m and R 1.05bn in 2018 (40.6m euros to 65m euros).

Private sector opportunities

- 5.23 We focus in this subsection on EHR systems, as billing systems are already an established technology in South Africa. Entrants to the billing system market would have to offer something particularly innovative, or to offer billing as part of a wider package of services, for example, integrated billing and EHR systems.
- 5.24 Mediclinic is in the process of selecting an EHR for their South African hospitals, after rolling out the first phase of implementation of an EHR and Patient Data Management System (PDMS) in their Swiss hospitals. Evaluation of the different EHR options is set to take place in 2020²¹.
- 5.25 We understand that Mediacross, the primary care division of Netcare, is in the process of piloting Med-e-Mass's HEALTHone EHR system, which integrates with a cloud-based billing system, Elixir Live, also provided by Med-e-Mass. We expect the EHR to be rolled out in Mediacross nationwide in the next 18-24 months.
- 5.26 Life Healthcare's 2018 annual report notes that a comprehensive cyber security

²⁰ Philips Future Health Index. (2018). *South Africa Local Market Special Report #2 Data Collection and Analytics*. Accessible at <https://www.philips.co.za/c-dam/corporate/newscenter/za/2018/FHI18-South-Africa-Special-Report-2.pdf>

²¹ Mediclinic (2018). *Annual Report*. Accessible at: http://annualreport2018.mediclinic.com/pdf/Mediclinic_Annual_Clinical_Services_2018.pdf

strategy and integrated electronic clinical systems will be a key focus area in the coming year (2019).²² However, there is not yet information on the selection process for their supplier of EHR systems.

- 5.27 Interviews with management of the smaller private hospital groups revealed that EHRs were also a very high priority for these groups, with more complex data analysis technologies to follow once the underlying data capture infrastructure is in place.
- 5.28 The most promising EHR opportunities in the private sector therefore lie primarily with the smaller hospital groups and independent hospitals, and with primary care provider groups (excluding Mediacross). There may also be opportunities with individual doctors and smaller practices, especially with the move away from the solo GP model towards group practices, but these will require more significant marketing investment.
- 5.29 While there is no immediate demand for Routine Health Management Information systems, and other advanced data analytics systems, in the market currently, this subsector offers more potential in some ways than EHR systems, because there are no established providers. While EHR systems are bedding down and an electronic database is being created, there is an opportunity to start building relationships with the major players (likely the large hospital groups), and understanding their needs, in order to be well positioned when these systems start to be procured in one to three years' time.

Public sector opportunities

- 5.30 Going forward, the largest opportunities relate to potential NHI contracts. While detailed information on plans for the implementation of NHI has not been published, it is possible that the NHI Fund will put out a tender for a national EHR system (covering primary care and/or hospital care). We understand that the NHI Fund will want to see evidence of technologies working at scale in the South African healthcare system, or in other countries with similar systems. As such, demonstrating successful rollout, either at the provincial level or in the private sector, will be key to securing NHI contracts.
- 5.31 As in the private sector, implementation of more sophisticated health management information systems in the public sector will be contingent on the reliable and consistent capture of the underlying data, and EHR rollout to public sector clinics and health centres will depend on the requisite ICT infrastructure and training. Once the underlying data is being collected, more advanced data analysis systems can be trialled and scaled up.

Summary of opportunities

- 5.32 Table 2 below highlights key opportunities in this area.

²² Life Healthcare (2018). *Annual report*. Accessible at: https://www.lifehealthcare.co.za/media/2520/life_healthcare_integrated_report_2018.pdf

Table 2: Summary of opportunities in the Data Capture Technology market

Subsector	Opportunity	Potential buyers	Existing players in SA
Electronic Health Records	EHR software – private sector	Smaller hospital groups; primary care provider groups; GP and specialist practices	Med-e-Mass; Meditech; Delta 9
	EHR software – public sector	NHI Fund	As above
Routine Health Management Information	Advanced data analysis systems	Large hospital groups	

6. Communication and knowledge transfer technologies

- 6.1 This grouping includes the following subsectors: health knowledge management; mHealth; telemedicine; and virtual healthcare. Solutions in this space range from more basic technologies, such as SMS services, to more sophisticated app-based communication platforms.

Growth drivers and barriers

- 6.2 Trends driving the need for communication technologies include:
- Shortage of healthcare workers, especially in semi-urban and rural areas;
 - Need for better access to healthcare information, both by medical staff and patients; and
 - Increase in the prevalence of chronic conditions with more complicated care pathways and the need for better, more joined-up case management.
- 6.3 Healthtech communication solutions can help to address these issues by offering virtual connection between patients and doctors, and between general practitioners and specialists, and by offering new channels (both push and pull) for the dissemination of health information.
- 6.4 However, these trends are countered by a number of obstacles to roll out of virtual healthcare solutions, including internet connectivity, the current regulatory framework, for example, the restrictive ethical rules of the Health Professions Council South Africa (HPCSA) which currently prevent a doctor from treating a patient he/she has not seen, and, most significantly, the difficulty of persuading healthcare professionals to use new technology. The issue of user adoption was raised frequently in our interviews by both healthcare funders and technology manufacturers.

Key players

- 6.5 There are a number of South African start-ups currently operating in this space, including Signapps (mobile app-based case management software), Vula (mobile app-based referral software), MomConnect (SMS-based health maternal and child health promotion) and Hello Doctor (mobile app-based health information and telephone doctor access).
- 6.6 This is an area in which the national and provincial health departments are major potential buyers, as the shortage of healthcare workers and the need to provide services in rural areas are more significant challenges in the public sector. This is evidenced by the success of MomConnect, which has been rolled out as a National Department of Health initiative.²³ MomConnect had a cumulative total of 1,700,000 registered users by 2018 and received an average of 250 helpdesk

²³ National Department of Health (2019). *MomConnect*. Accessible at <http://www.health.gov.za/index.php/mom-connect>

queries per day.²⁴

- 6.7 In the private sector, both funders and providers of healthcare present potential markets, as major funders (schemes or administrators) can make using a particular platform a condition of doctor network membership, for example, while doctor groups and facilities also make purchasing decisions themselves for these types of technologies.

Estimated size of the market and potential opportunities

- 6.8 Andrew Davies, the CEO of Signapps, believes that the potential market for care coordination software in South Africa is huge; Signapps itself is targeting annual turnover of licensing fees of R 100m by 2024 (5m euros). He observed that there is a global problem to solve around effective case management (where a patient's journey along the care pathway is smooth and supported), and while unable to put an exact figure on the total potential market for software which helps to address this in South Africa, Andrew estimates that it runs into the billions of rand.
- 6.9 As suggested by the number of home-grown start-ups in this space, the competitive environment for communication and knowledge transfer technologies is fierce. However, it may be possible for companies to differentiate themselves by offering a solution that is tailored to healthcare. Andrew Davies attributed the recent success of Signapps in concluding a deal with Life Healthcare, in the area of stroke communication management, to the healthcare-specific features offered through the platform. He also noted that there is a big opportunity for technology solutions which allow for more unstructured interactions and which reflect how health professionals and patients would naturally communicate.
- 6.10 South Africa provides a good launchpad for technologies which help to solve issues relating to staff shortages and rural service provision, for example, telemedicine and virtual healthcare technologies which enable doctors and patients, and doctors and other health professionals, to communicate without being in the same location. These problems are even more acute elsewhere in Africa, and simpler technologies which prove successful in South Africa could expand into other neighbouring markets, as these are potentially better suited to meeting needs in a developing country health system context than more sophisticated solutions developed in, say, the US and Europe.
- 6.11 It was also suggested in the interviews that South Africa provides a lower cost testing ground for the development of health technology solutions because, while complex and problematic in some areas, the regulatory environment in South Africa is less stringent than more developed economies, for example, the US.
- 6.12 Following criticism from the Health Market Inquiry, the HPCSA are undertaking a review of their ethical rules for members, and specifically looking at the rules relating to telemedicine and multi-disciplinary teams. If those changes are made, this would unlock huge pent-up demand for both virtual healthcare-type solutions

²⁴ Barron P, Peter J, LeFevre AE, et al (2018). *Mobile health messaging service and helpdesk for South African mothers (MomConnect): history, successes and challenges*. BMJ Global Health. Accessible at https://gh.bmj.com/content/3/Suppl_2/e000559

and technologies which facilitate team-based working.

Summary of opportunities

6.13 Table 3 below highlights key opportunities in this area.

Table 3: Summary of opportunities in the Communication and Knowledge Transfer Technologies market

Subsector	Opportunity	Potential buyers	Existing players in SA
Telemedicine	Technology to enable virtual doctor-patient consultations	GPs and specialists; public sector; hospital groups	
	Referral tools (between nurses/GPs and specialists)	GPs and specialists; public sector	Vula
Virtual healthcare	Multi-disciplinary team communication tools	GPs and specialists; public sector	Signapps
	Technology to optimise patient journey	Medical aid schemes; public sector	

7. Consumer health technologies

- 7.1 This subsection deals with consumer health informatics and health and activity tracking wearable devices (“wearables”). Consumer health informatics are technologies which allow access to information on health by healthy individuals and aim to put consumers in charge of their own healthcare, by making use of personalized data, informatics tools and systems.
- 7.2 Under this definition, wearables is actually a subgroup within consumer health informatics, but we discuss the two separately because of the specifics of the wearables market. There is also some overlap between consumer health informatics and mHealth technologies discussed in the previous section, for example, where health information is ‘pushed’ to subscribers via SMS.

Growth drivers and barriers

- 7.3 The rise of consumer health informatics is being driven by a number of global trends, including:
- i) Consumers/patients wanting more access to and control over their health information, and feeling more entitled to that access;
 - ii) Growing awareness of the need to equalise relationships between health professionals and lay people (the “end of paternalism”)²⁵;
 - iii) Rise of so-called “lifestyle diseases” and growing awareness of the links between health and behaviour;
 - iv) Advances in genetic testing, and increased affordability, resulting in rising popularity of genetic testing for ancestral lineage, disease predisposition and mutant genes, for example, to find evidence of, or rule out, inherited disorders; and
 - v) Consumer-led demand premised on incentives offered by life insurers’, health care funders’ and employer-led incentive programmes.
- 7.4 In this context, the use of wearable devices to generate personalised health information is becoming increasingly popular. This specific trend is being encouraged by a number of factors, including:
- i) Decreasing cost of devices making them affordable to more people;
 - ii) Technological advances which make wearables less obtrusive and more integrated into everyday life;
 - iii) Value of members’ health data to life insurers, medical aid schemes (and their administrators) and employer wellness programmes, leading to incentive schemes to drive uptake; and
 - iv) Data-driven exercise tracking (e.g. goal monitoring) becoming an increasingly popular way to train, along with rising popularity of exercise-centric social

²⁵ See for example Coulter A, “Paternalism or partnership? Patients have grown up-and there's no going back.” BMJ. 1999

media platforms (e.g. Strava).

- 7.5 However, it is possible that this growth in the rapid growth of wearables will level off, as it is as yet unclear whether the popularity of the concept will expand beyond a small group of already relatively healthy individuals. Further, in South Africa, the proportion of the population with sufficient income levels to consider purchasing a wearable device is limited.

Key players

- 7.6 Given their nature, the main purchasers of consumer health informatics technologies are individual consumers. However, because they have an interest in their population staying healthy, healthcare funders are also potential customers, either as direct purchasers or through offering subsidies and incentives to consumers/patients.
- 7.7 In an example of this, in South Africa, the market for health tracking wearables is shaped in large part by the medical aid scheme administrator Discovery Health. Discovery Health is the administrator of the largest open medical scheme in South Africa, Discovery Health Medical Scheme (DHMS), and it also acts as an administrator for another 18 restricted schemes.
- 7.8 Discovery Health offers an incentives-based behavioural change programme called Discovery Vitality, aimed at improving members' health and wellness. Members can earn points by being physically active and exchange these points for rewards ranging from coffee to retail store vouchers.
- 7.9 To track physical activity, Vitality members can use wearable devices, including smart phones and watches, GPS trackers and heart rate monitors. Importantly, it is only possible for members to link their account (via a cloud-based device platform) to a Vitality-recognised wearable; Vitality only certifies particular brands and even particular models within a brand. Vitality currently recognises wearables from Apple, Garmin, Suunto, Fitbit, Huawei, Polar, Withings and Samsung.
- 7.10 Further, the Vitality programme subsidises the purchase of wearables, conditional on beneficiaries meeting their activity goals. Currently, Vitality offers discounts on selected models from Fitbit, Garmin, Polar, Suunto and Huawei wearables, including a low-cost option which is reimbursed fully by Vitality if activity goals are met. There is also an option with Apple where an Apple watch is provided up front and the member only has to make repayments on the watch if they do not meet their exercise goals.²⁶
- 7.11 Given that Discovery Health has a market share of 40% in the overall medical schemes market and that the subset of South Africans who are members of a medical aid scheme are typically wealthier, with more disposable income, the decision of Vitality to recognise and subsidise certain wearables determines to a large extent their uptake in the market. As such, the commercial contract between Vitality and the device manufacturer often includes rebates for Discovery.
- 7.12 When Vitality considers a wearable, they undertake a process of due diligence on

²⁶ For all other devices, Vitality offers 75% of the device's value earned back by meeting activity goals, up to a ceiling of R 4,000 (250 euros).

the wearable itself and the vendor/manufacturer. The five main areas considered are:

- i) **Consumer brand:** This is the first thing Vitality considers; Vitality has rejected approaches in the past from companies with potentially superior technology but without broad consumer appeal, suggesting that consumers are highly brand conscious.
- ii) **Reliability and national support structure:** It is important for the Vitality brand that the device be reliable. They therefore consider the retail footprint of the device vendor/manufacturer and how easily a member is going to be able to get a device fixed.
- iii) **Functionality:** The minimum requirements are that the device be able to i) count steps and ii) monitor heart rate (because the Vitality physical activity points are awarded on the basis of number of steps taken and length of time spent at an elevated heart rate level).
- iv) **Ease of technical integration:** How easily will the device and its software (e.g. Samsung Health, Apple Health) integrate with the Vitality system.
- v) **Data protection:** The vendor/manufacturer must be able to ensure that the member's data will remain secure.

Estimated size of the market and potential opportunities

- 7.13 The market for wearables in South Africa is relatively mature, with a variety of devices sold nationally and recognised by Vitality. Rough estimates, based on limited information from Vitality, put the size of the South African market for wearables in the region of R 400m (25m euros) in 2018²⁷. Given the number of established brands in the wearables market in South Africa, a new entrant would need to be able to need to put forward an innovative and distinctive offering.
- 7.14 According to Vitality, a new entrant could differentiate itself by offering two things: i) fraud mitigation technology; and ii) a creative incentive/rebate package. In the view of Vitality, none of the current brands have invested sufficiently in fraud mitigation technology and it is not difficult for the 1% of people who want to 'cheat' to do so. Manufacturers could also differentiate themselves by putting together a creative commercial offering, e.g. through the rebate structures for members and Vitality, shared destiny models, financing arrangements etc.
- 7.15 In addition to physical activity, Vitality is looking to expand its rewards programme to incentivise activities which promote mental wellbeing. We understand the Vitality clinical team are currently evaluating the effectiveness of mental wellbeing apps and that Vitality is looking to recognise both sleep tracking technologies, as well as meditation in 2020. These markets are more immature and represent areas of opportunity.
- 7.16 Outside of the Vitality system, there is also potential for growth in nutrition tracking devices, such as blood glucose monitoring systems and breath ketone

²⁷ Based on consumer health tracking devices including the Apple Watch sold by Discovery Health through Vitality.

meters, which have gained popularity internationally with diet trends, such as ketogenic diets.

7.17 Genetic testing facilities are available at eight national universities, the National Health Laboratory Service, as well as Ampath and Lancet laboratories and other private screening providers.

Summary of opportunities

7.18 Table 4 below highlights key opportunities in this area.

Table 4: Summary of opportunities in the Consumer Health Informatics market

Subsector	Opportunity	Potential buyers	Existing players in SA
Consumer health informatics	Sleep tracking technology	Consumers (potentially subsidised by Vitality)	
	Meditation apps	Consumers (potentially subsidised by Vitality)	
	Nutrition tracking technology	Consumers	
Wearables	Wearable with fraud mitigation technology	Consumers (potentially subsidised by Vitality)	None
	Fraud mitigation technology	Wearable manufacturers	None
	Wearable with creative commercial offering to Vitality	Consumers (potentially subsidised by Vitality)	

8. Artificial Intelligence and Robotics

- 8.1 This section deals with both Artificial Intelligence and Robotics, distinct technologies with a small area of overlap (artificially intelligent robots).
- 8.2 We use a broad definition of Artificial intelligence (AI) to mean computer programs or algorithms which complete tasks which would otherwise require human intelligence, including learning, perception, problem-solving, language-understanding and/or logical reasoning. In the healthcare space, we focus on the use of advanced statistical analysis of healthcare data for the following purposes:
- i) Providing clinicians with support in diagnosis and treatment decision-making. These tools vary in sophistication, how interactive they are and what sort of inputs they require, e.g. quantitative and qualitative information, images.
 - ii) Building Information Modelling (BIM) and improving patient flow in facilities, for example, the use of computer imaging systems and statistical analysis to aid in the design and upgrading of facilities, as well as triage systems to distribute patient load optimally.
 - iii) Advanced therapeutic technologies, for example, precision medicine (the targeting of interventions specific to the individual (based on genetic testing or other screening)) and DNA printing (artificial gene synthesis for the purposes of, for example, vaccine development and gene therapy).
- 8.3 Robotics is the branch of technology which deals with robots, programmable machines which are usually able to carry out a series of actions autonomously, or semi-autonomously. We focus on the following technologies in the healthcare context:
- i) Advanced imaging technology (increasingly being used as a guidance tool during surgery, as well as for diagnostic purposes). Examples include interventional or interoperative MRI scanning, which can help surgeons to determine, during surgery, whether a tumour has been fully removed.
 - ii) Robotic surgery: robotic tools can help to improve accuracy and minimise invasiveness.
 - iii) Teaching tools. Imaging and robotic systems are combined to simulate surgery for the purposes of training. As well as allowing students to train with no potential adverse effect on patients, robotic teaching tools can also help to alleviate teaching staff shortages.
 - iv) Automated delivery and dispensing, for example, of blood products or pharmaceuticals. Drone delivery of blood supplies to remote rural areas is becoming a cost-effective solution, which robotic medicine dispensing machines can provide chronic medication in convenient locations and at any time of the day. These robotic dispensing machines label and dispense medication after confirming the identity of the recipient.

Growth drivers and barriers

- 8.4 Globally, AI and robotics are being used increasingly in the healthcare sector.

Owing to their significant cost however, the majority of AI and robotics technologies will only find a market in South Africa in the well-resourced private sector. However, there may be public sector interest in a minority of technologies which either reduce costs or help to solve problems which are particularly acute in the public sector, for example, the challenge of service provision in rural areas.

8.5 The main drivers of growth in demand for these technologies include:

- i) Demand for the best available treatment. As the internet enables patients and specialists to become better informed about globally available technologies, both groups exert pressure for the latest treatments to be available in South Africa. Further, private hospitals offer specialists access to the latest and best equipment in order to encourage the best specialists to operate within their facility.
- ii) Skills shortages. There are shortages of almost all types of healthcare practitioners in South Africa, particularly in the public sector. Technologies which can increase the productivity of existing staff, or perform tasks which reduce the number of staff required, for example, in radiology or dermatology, can alleviate the impact of these staff shortages on patients.
- iii) Pressure to reduce cost. This is key factor in both the public and private sectors, as providers come under increasing pressure from funders. Demand for AI and robotic solutions which help providers to deliver services more cheaply will be significant.
- iv) Challenge of service delivery in rural areas. Related to the shortage of healthcare workers and cost constraints, providing services in remote, sparsely populated areas of the country presents a significant challenge, primarily for the public sector. Innovative technology can reduce the need for patients or clinical staff to travel long distances, and provide more cost-effective solutions for the delivery of supplies.
- v) Increase in chronic disease prevalence. The number of people requiring chronic disease medication is increasing, as a result of the HIV epidemic as well as the rise of non-communicable diseases, such as diabetes. There is an acute need for more efficient and convenient solutions for medication dispensing, for example, automated pharmacy machines.

8.6 However, there are also a range of barriers to greater implementation of AI and robotics in South Africa, including the high cost of many of these solutions in a resource-constrained environment, poor internet connectivity in many health facilities, lack of appropriate solutions for the South African context and potential resistance from both patients and practitioners to the use of computer-led diagnosis and treatment interventions. In addition, there is currently neither legislation nor precedent to govern liability or professional negligence in the case of harm to a patient resulting from a decision was prompted by a computer system rather than a clinician's judgement. This is an area in which legislation lags behind technological developments globally.

8.7 The limitations of current data collection, in both private and public sector facilities, is a further barrier to the implementation of sophisticated AI analytical tools, as is the lack of interoperability between databases in different facilities and

practices.

Key players

- 8.8 In terms of potential purchasers of AI and robotic technologies, the large hospital groups are the most likely significant purchasers, followed by smaller hospital groups and specialists. In terms of technologies which improve chronic disease management (or decrease cost), medical aid schemes and scheme administrators may be potential customers.
- 8.9 The public sector is potentially a large purchaser of automated delivery and dispensing technology (as evidenced by the South African National Blood Service's use of drones to deliver blood supplies to rural areas), as well as of other technologies which reduce cost or mitigate staff shortages.
- 8.10 There are a number of local specialised diagnosis and therapy tool companies in South Africa, some of which form part of the Cape Health Technology Park. Some key players include:
- i) CapeRay, inventors of the Aceso system, a dual X-ray and ultrasound device for breast cancer detection;
 - ii) Lodox, producers of a full-body, high-speed imaging system with low radiation and emission scatter for trauma centres and forensic pathology units; and
 - iii) Impulse Biomedical, a device manufacturer focused on creating devices to increase access to healthcare.
- 8.11 Lodox and Cape Ray as case studies indicate that local South African producers can successfully compete in international markets, if they have access to the appropriate funding channels.²⁸ Both companies have expanded internationally: Lodox has installed versions of their full-body imaging system in Baltimore, Minnesota, Singapore, Switzerland, Tennessee and the UAE.
- 8.12 The South African Medical Research Council has partnered with the University of Cape Town to investigate ancestral groupings in the current populations of Southern Africa, and related susceptibility/resistance to disease, with a view to applying precision medicine and enhancing the targeting of interventions to improve health outcomes.
- 8.13 Other local ventures include the Mobile Triage App, developed by the Open Medicine Project, which assists in sorting patients according to urgency in emergency rooms, and Right ePharmacy, which has five automated pharmacy dispensing machines operational in South Africa.
- 8.14 We are not aware of any providers of DNA printing currently in the South Africa market. Whilst home genetic testing is available, along with genetic testing at pathology laboratories, we are not aware of large-scale DNA printing or biologics

²⁸ Lodox was commercialised from the De Beers mining company's need for a scanning system to prevent staff stealing diamonds. The research and development was a joint venture with the University of Cape Town, and funded, in part, by an Innovation Fund grant.

manufacturing taking place in South Africa.

Estimated size of the market and potential opportunities

- 8.15 The large private hospital groups in South Africa are using high-tech surgical robotics. For example, Intuitive Surgical's da Vinci surgical robotic technology is used at three Netcare hospitals to treat localised prostate cancer, and Life Healthcare makes use of Alliance Medical's imaging tools including radiopharmacy, that allows the identification of cancers in highly specific areas of the body by deploying radioactive isotopes that show up in PET scans. There is lower implementation of AI solutions currently, but there are some examples, e.g. Mediclinic has recently installed Philips' connected care enterprise monitoring and patient care solutions in 21 of its hospitals, which will enable big data analysis.
- 8.16 Lack of data collection systems in South Africa's smaller private hospital groups mean that they are yet to adopt AI and big data analysis, although they have plans to do so.
- 8.17 Current decision support mechanisms, for example, the Essential Medicine Guidance app, in South Africa are basic, and do not make use of AI. There are therefore opportunities for more sophisticated solutions to enter the market. Similarly, robotic and augmented reality teaching aids could readily find a market in South Africa, if they are seen to either enhance current teaching methods and/or can be used to address teaching staff shortages.
- 8.18 In terms of medical imaging, while there is significant innovation in the domestic market, commercialisation of these technologies has proven difficult, due in part to the relatively small size of the South African private sector healthcare market. For example, CapeRay, which developed a combined X-ray and ultrasound breast imaging technology for the early detection of cancer, secured ISO 13485 certification and the CE mark in 2012 before launching in the European Union, the Middle East and South Africa. Launching in South Africa alone was not commercially viable, so regulatory approval had to be sought in other regions, delaying commercial launch. This is a possible area for collaboration between Dutch and South African firms. Collaboration may allow a Dutch company with access to larger markets to leverage off South Africa's relatively lower cost of research and development.
- 8.19 Importantly, current SAHPRA regulations effectively make market access for internationally manufactured devices easier than for South African manufactured products. This is because if products are manufactured in South Africa, demonstrating compliance with the Essential Principles is more difficult; in addition to the long waiting times for SAHPRA certification, South Africa lacks sufficient manufacturing infrastructure that is ISO 13458 certified, as well as the infrastructure required to produce products at scale.

Summary of opportunities

- 8.20 Table 5 below highlights key opportunities in this area.

Table 5: Summary of opportunities in the AI and Robotics market

Subsector	Opportunity	Potential buyers	Existing players in SA
AI	Diagnosis and treatment decision support systems	GPs and specialists; facilities	EM Guidance
	Precision medicine	GPs and specialists; facilities (private sector)	
	DNA printing	GPs and specialists; facilities (private sector)	
Robotics	Advanced imaging	GPs and specialists; facilities (private sector)	CapeRay, Lodox
	Robotic and augmented reality teaching tools	Universities	
	Automated delivery and dispensing	Public sector	Right ePharmacy; SANBS

9. Summary of subsector analysis

9.1 Figure 12 below summarizes our analysis of the individual subsectors, rating potential demand and existing supply in each subsector as either High, Medium or Low.

Figure 12: Priority Sector Analysis

Sector	Subsector	Demand	Existing supply	Detail
1 Data Capture	EHR	High	Medium	Private sector has begun EHR adoption. Public sector has fragmented adoption
	Routine health management information	High	Low	Once EHR systems are in place, big opportunity for analysis systems using captured data
	Vital registration	Low	Low	Never mentioned as major growth area, although may be potential for electronic death certification
2 Communication and knowledge transfer	Health knowledge management	Low	Low	Not aware of any existing solutions but also never mentioned as major growth area
	mHealth	Medium	Medium	May be overtaken by more sophisticated app-based tech. Some existing solutions (MomConnect) in market. But given infrastructure constraints, still potential for reliable low-tech solutions, esp in public sector
	Telemedicine	High	Low	Skills shortages mean lots of scope for telemedicine. Underexploited so far because of HPCSA rules, which are about to change
	Virtual healthcare	High	Medium	Complex chronic conditions require team-based management. As prevalence rises, lots of scope for technology which facilitates this
3 Consumer Health	Consumer Health Informatics	Medium	Low	Some specific opportunities related to Vitality; some other general opportunities
	Health tracking wearables	High	High	Market already mature but some potential for new brands to differentiate themselves in SA
4 Artificial Intelligence	Diagnosis and treatment decision support	High	Low	High potential demand without established players, but user adoption will be key challenge
	BIM and patient flow management	Medium	Medium	Some BIM solutions in SA market. Triage systems require better underlying data
	Advanced therapeutic technologies	High	Medium	Some technologies available but not at scale. Potential for collaboration with SA research
5 Robotics	Advanced imaging	Medium	Medium	Some local demand, depending on cost of solution, but small market. Potential for collaboration with SA research
	Robotic surgery	Medium	Medium	Private sector deploying in some hospitals, room for expansion. Cost prohibitive for public sector.
	Teaching tools	High	Low	Potential market for robotic teaching aids, if enhance current teaching and/or mitigate staff shortages
	Automated delivery and dispensing	High	Medium	Significant opportunities in public sector. Some existing players in market

10. Market entry strategies

- 10.1 Deciding on how and when to enter a new market is a crucial decision for a firm wishing to expand across borders. In this section we describe some of the possible market entry strategies that may be suitable for Dutch firms wishing to enter into the South African market.
- 10.2 As noted in Section 4, it is important to bear in mind that, owing to the concentrated nature of the South African economy, with many sectors dominated by relatively few players, sustained market development is required to overcome a conservative market bias that tends to prefer known suppliers.
- 10.3 There are six factors which strongly predict success in market entry. These are laid out in Table below.

Table 5: Factors predicting success in market entry

<i>Predictor</i>	<i>Description</i>
Size of entry relative to minimum efficient scale	Companies that are closer to an industry's minimum efficient scale upon entry are much more likely to succeed. Entering below minimum efficient scale and then quickly scaling up is more viable when companies test a new market than as part of a plan for gradual growth
Relatedness of the market entered	The more related the market is to a company's current portfolio of products and services, the greater the chance of success.
Complementary assets	Core assets and capabilities are important when entering a new market. However, complementary assets, such as marketing and distribution, are often more important factors for success than core assets, such as engineering prowess.
Order of entry	While first movers have the advantage over laggard rivals in some settings, greenfield and diversifying companies are on very different clocks. Early greenfield entrants often are optimistic martyrs, losing out to experienced players that diversify into the market leader.
Industry-life-cycle stage	The life-cycle of an industry when a company enters is easily determined and greatly influences opportunities for success. Companies entering early in an industry's life cycle have greater odds for success than those entering near the shakeout.
Degree of technological innovation	When a high level of inside industry knowledge is necessary to innovate, incumbents have a major advantage over new entrants. When outside knowledge is essential, entry is easier. Innovative entrants are more likely to succeed by staying in small niches that dominant players ignore rather than by expecting to compete with them as equals.

Source: Adapted from Horn, Lovallo and Viguerie (2005). Beating the odds in market entry.

- 10.4 Regarding the sectors identified above, we note that there is scope for entry into subsectors of all four categories; data capture technologies, communication and knowledge transfer technologies, consumer health technologies, and artificial intelligence and robotics. This is because many of these high-technology markets are far younger in South Africa than in the Netherlands, and as such, Dutch companies are likely to have advantages for each of the six predictors noted in

Table . In particular, many subsectors are characterized as early in their industry-lifecycle, are related in nature to existing Dutch healthtech markets, and require technical innovation that Dutch healthtech companies are well equipped to provide.

- 10.5 For some sectors, older Dutch technology that has previously been developed and optimized in other markets could be profitably rolled out in South Africa at relatively low cost. For example, due to South Africa's poor broadband connectivity but high rates of cellphone ownership, mHealth interventions that make use of low-tech USSD codes would still be useful and applicable in South Africa for the next five to ten years, before app-based solutions supersede these.
- 10.6 Complementary assets such as marketing and distribution will be important in effectively entering the market. These strategies are discussed below by model of market entry.
- 10.7 When a firm has decided to enter an overseas market, there are a variety of options open to it. These options vary with cost, risk and the degree of control which can be exercised. Three required decision relate to:
- i) Marketing – which segments of the market are most profitably pursued, should marketing be done directly or through an intermediary.
 - ii) Sourcing – should products be manufactured fully in the Netherlands and exported, constructed partially in South Africa, or fully manufactured in South Africa. For software products sold as a service, to what extent is it necessary to position full time technicians in South Africa.
 - iii) Investment and control – paths to entry include embarking on a joint venture, licensing, consortium or acquisition of an existing firm active in the South African market.
- 10.8 There are five market entry strategies that are appropriate for Dutch firms wishing to enter the South African health technology market. These are listed below along with their characteristics.

Direct Exporting

- 10.9 Often the most obvious market entry strategy, exporting fully manufactured products to an overseas country has clear advantages. Manufacturing is maintained in the country of origin, involving less risk than investing in overseas production facilities. Exporting allows a firm to 'learn' external markets before making significant investments. However, disadvantages include the fact that direct exporters have limited control over the distribution of their product in the external market, relying heavily on agents.

Licensing and franchising

- 10.10 Franchising works well for firms that have a repeatable business model, a well-known brand, or a unique offering. Licensing, in the context of health technology, involves licensing a product to a firm in a foreign country to manufacture and distribute in that country. This route to market requires little expense and involvement. It is also a low risk way to establish manufacturing relationships: a firm's capital is not tied up in a foreign operation, and there is the option to

purchase into the licensed operation in time.

10.11 However, given the constraints discussed above regarding South Africa’s limited medical device manufacturing infrastructure (and lack of facilities with ISO 13485 certification), there are also disadvantages associated with licensing. Further, licensing is a limited form of participation (usually a specific product, process or trademark is licensed for a limited length of time), and there is the necessary transfer of knowhow to a licensee, with the risk that the licensee becomes a competitor with no wish to renew the license.

Partnering and joint ventures

10.12 Partnerships, and the specific sub-type known as a joint venture, are more extensive forms of market participation than either direct exporting or licensing. Partnering can take a variety of forms, from a simple co-marketing arrangement to a sophisticated strategic alliance for manufacturing. Joint ventures are a sub-type of partnership and can be defined as an enterprise in which two or more investors share ownership and control over property rights and operation.

10.13 The advantages of partnerships and joint ventures include the sharing of risk and the ability to combine local knowledge of the South African market with Dutch technological know-how. Further, joint ventures provide for the possibility of supplying a third country, making use of existing trade channels. For instance, South Africa serves as an export hub for medical devices to sub-Saharan Africa. Goods are imported into South Africa before being transported via existing trade routes to neighbouring African countries. As shown in Figure 13, below, medical instruments and devices, as well as electronic imaging devices, are both re-exported from South Africa.

10.14 As shown in Figure 14, below, the top four destinations for exports of medical instruments and devices, and electronic imaging devices between 2010 and 2019 were all neighbouring countries; Namibia, Botswana, Zimbabwe and Swaziland.

Figure 13: South Africa's Re-Exports of Medical Technologies (2010-2019)

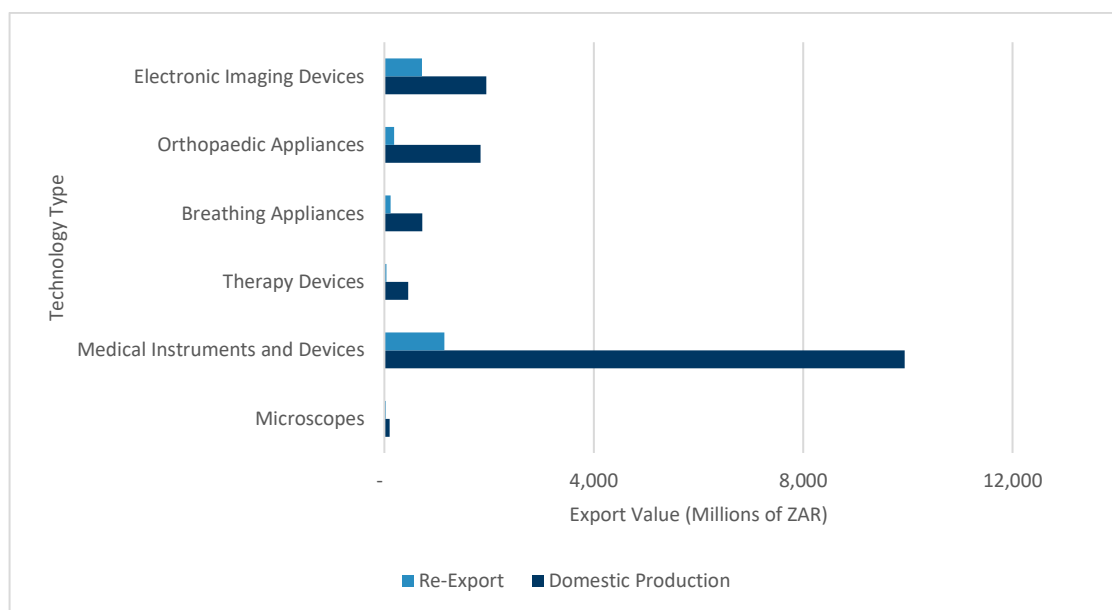
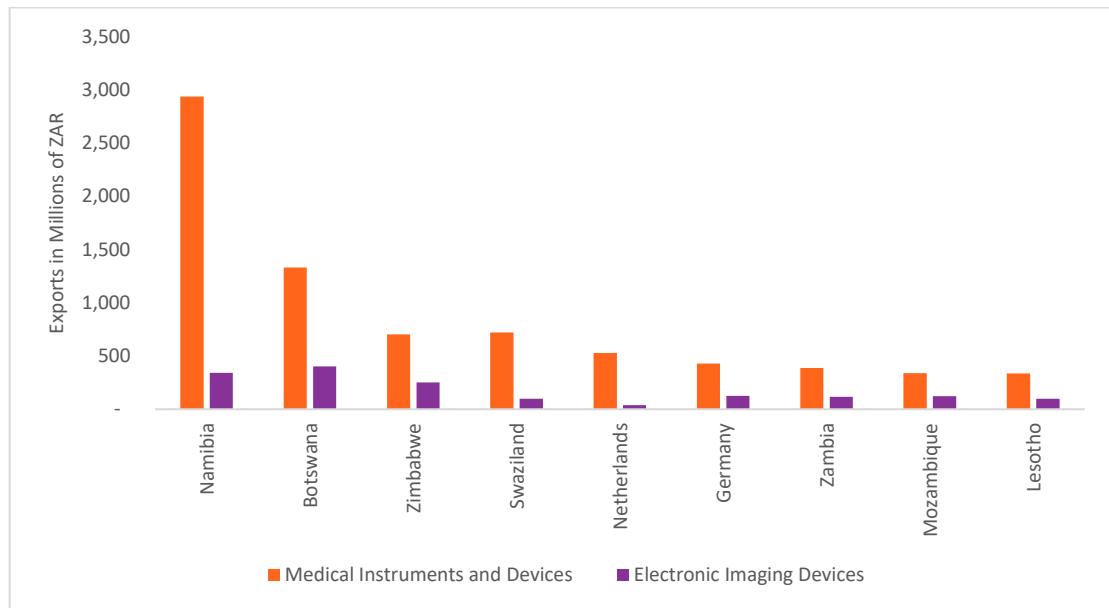


Figure 14: Destination of medical technology exports from South Africa (2010-2019)



Source: FTI Calculations, SARS Merchandise Trade Statistics

10.15 There are however disadvantages to joint ventures. First is the fact that by definition, partners do not have full control of management. Second, partners may have different views on expected benefits, putting strain on the commercial relationship between partners.

Buying a company

10.16 In some cases, purchasing an existing company would enable a health technology firm to reach a foreign market quickly. The advantages are that the acquired firm may already have high market share, or may have market access through government regulation (e.g. because of its B-BBEE status) that would otherwise be difficult to acquire. Other advantages include access to local market knowledge and a local customer base. However, this is a costly way to enter the market, and assessing the value of an acquired firm would require substantial due diligence.

Greenfield investment

10.17 Greenfield investments in a foreign country require the greatest involvement from a health technology provider. This involves investing in an entirely new operation in the foreign country; purchasing land, building facilities, and operating the business on an ongoing basis. This is also a costly way to enter the market, well suited to larger companies that have the expertise to overcome government regulations, transport costs, and the ability to access technology and skilled labour in the foreign market.

11. Conclusion

11.1 The analysis presented above suggests that there are significant opportunities for growth in the South African healthcare technology market, with some subsectors offering greater potential than others. We have identified some particularly promising opportunities, as well as possible market entry strategies that Dutch companies could pursue. Table 6 below combines these two components and suggests which market entry strategies would be most suitable for the specific opportunities identified.

Table 6: Market Entry Analysis

Sector	Subsector	Opportunity	Recommended Market Entry Strategies
Data Capture	Electronic Health Records	EHR software – private sector	Direct exporting; Licensing and Franchising
	Electronic Health Records	EHR software – public sector	Direct exporting; Licensing and Franchising
	Routine Health Management Information	Advanced data analysis systems	Direct exporting; Licensing and Franchising; Partnering and Joint Ventures
Communication and Knowledge Transfer	Telemedicine	Technology to enable virtual doctor-patient consultations	Direct exporting; Licensing and Franchising
	Virtual healthcare	Referral tools (between nurses/GPs and specialists)	Partnering and Joint Ventures; Buying a Company
	Virtual healthcare	Multi-disciplinary team communication tools	Partnering and Joint Ventures; Buying a Company
	Virtual healthcare	Technology to optimise patient journey	Direct exporting; Partnering and Joint Ventures
Consumer Health Technologies	Consumer health informatics	Sleep tracking technology	Direct exporting
	Consumer health informatics	Meditation apps	Direct exporting
	Consumer health informatics	Nutrition tracking technology	Direct exporting; Licensing and Franchising
	Wearables	Wearable with fraud mitigation technology	Direct exporting
	Wearables	Fraud mitigation technology	Direct exporting; Licensing and Franchising
	Wearables	Wearable with creative commercial offering to Vitality	Direct exporting
Artificial Intelligence and Robotics	Artificial Intelligence	Diagnosis and treatment decision support systems	Direct exporting; Licensing and Franchising
	Artificial Intelligence	Precision medicine	Licensing and Franchising; Partnering and Joint Ventures
	Artificial Intelligence	DNA printing	Licensing and Franchising; Partnering and Joint Ventures

Robotics	Advanced imaging	Partnering and Joint Ventures; Buying a Company
Robotics	Robotic and augmented reality teaching tools	Direct exporting
Robotics	Automated delivery and dispensing	Direct exporting; Licensing and Franchising

12. Annex 1: Regulation of medical devices and technologies

12.1 As noted above, medical devices and technologies are regulated by the South African Health Products Regulatory Authority (SAHPRA). Below we explain the establishment of SAHPRA and the regulations which govern the sale of medical devices in South Africa.

SAHPRA and associated regulations

12.2 SAHPRA as established by the 2015 Amendment Act is tasked with regulating medicines, medical devices and IVDs, complementary medicines and radiation control. This is in contrast the MCC's mandate to regulate just medical devices with an electronic component. SAHPRA's mandate covers devices from simple syringes to magnetic resonance imaging machines.²⁹ The mandate of SAHPRA is to ensure that the products under its charge are safe, effective, of good quality and in the interest of the public throughout their life cycle.³⁰

12.3 SAHPRA both register devices and undertakes continuous monitoring and evaluation of devices as they are used. The rollout of SAHPRA's regulation of medical devices has been slower than for medicines, with the process for registration of medical devices started in June 2017, and the objective of completing registration of devices currently on the market in 2020.³¹

12.4 Medical devices are classified using a four-tier system, in ascending order of risk. SAHPRA's registration requirements correspond to these four tiers. The regulations require of all classes of device that a manufacturer, distributor or wholesaler obtains a "medical device establishment" licence before any device can be registered. For foreign-manufactured products, the regulations prohibit the importation of Class B, C, or D medical devices that are not registered in South Africa. In addition, sale of Class C and D medical devices require pre-market approval in by regulatory bodies in at least one of the following regions; Australia, Brazil, Canada, Japan or the European Community. This is expanded upon in a section on licensing, below.

12.5 Notably, this flexibility in registration of medical devices, whereby manufacturers, distributors or wholesalers can make use of verification of registration in other jurisdictions, is in contrast to the regulation of medicines by SAHPRA. For medicines, SAHPRA inspects the manufacturing plants where all medicines that are sold in South Africa are made, even those abroad.

12.6 Further, SAHPRA and the new regulations provide for expedited registration for instances in which devices are in short supply, unavailable, or in the national interest. In addition, the new regulations include a provision through which the government can consider in a tender international devices which are not yet

²⁹ Saidi, T., & Douglas, T. S. (2018). Medical device regulation in South Africa: The medicines and related substances amendment act 14 of 2015. South African Medical Journal. <https://doi.org/10.7196/SAMJ.2018.v108i3.12820>

³⁰ SAHPRA – Who or what is SAHPRA, May 2019, <https://www.mm3admin.co.za/documents/docmanager/editor/9400/UserFiles/who%20is%20sahpra.pdf>

³¹ Ibid.

registered in South Africa, circumventing the requirement that all devices considerable in a tender must be registered in terms of the Act.

Licensing for manufacturers

- 12.7 For a health technology to be marketed in South Africa a manufacturer, distributor or retailer must apply for a “medical device establishment” licence. The medical device establishment licence allows manufacturers, distributors or wholesalers to place a product on the market. Holders of these licences are legally responsible for the medical devices and IVDs on the market.

Registration of Medical Devices

- 12.8 Upon receiving a medical device establishment licence, manufacturers, distributors or wholesalers must register any new medical device on the medical device register prior to importation, supply or export of said device.

- 12.9 The requirements for registration include:

- Device classification that is proportional to the level of risk associated with a medical device or IVD, and based on the risk associated at point of usage.
- Products align with the “Essential Principles” for the quality, safety and performance of a product, both pre-market and while the product is marketed in South Africa. This includes an appropriate system for monitoring the ongoing performance and safety of the device.
- South African Conformity Assessment Body or international notified body for conformity assessment certifies that devices complies with essential principles.
- Inclusion in the registers for medical devices and IVDs.
- Ongoing monitoring of device while on the market.

- 12.10 The “Essential Principles”, or requirements for the quality, safety and performance of the medical device apply both before the product is marketed in South Africa, and while the product is supplied on the market. There are six general Essential Principles that apply to all devices, and a further nine relating to design and construction that apply on a case-by-case basis.

- 12.11 Importantly, SAHPRA does not prescribe how manufacturers must demonstrate that their products meet the Essential Principles. Rather, there is flexibility, allowing manufactures to use;

- Recognized standards, as discussed below. This the most common method to demonstrate compliance used in South Africa.
- A documented and detailed risk analysis
- The results of testing of the medical device
- Literature searches
- Copies of the label, packing and ‘Instructions for Use’ to demonstrate that the information requirements have been met

- Expert opinion
- The design dossier, if applicable.

Pre-market approval or registration from regulatory authorities

12.12 In an attempt to contain the cost of regulatory compliance, SAHPRA allows devices to be certified as compliant with the Essential Principles if they are registered in other jurisdictions according to recognised standards. Regulators in the following regions can be used; Australia, Brazil, Canada, Japan or the European Community.

13. Annex 2: Broad-Based Black Economic Empowerment

- 13.1 As discussed above, Broad-Based Black Economic Empowerment (B-BBEE) is a legislative framework the primary purpose of which is to address the legacy of apartheid and promote the economic participation of previously disadvantaged groups in the South African economy.³² The following section explains the B-BBEE system, including the carveouts for multinationals known as the Equity Equivalent Programs.
- 13.2 The generic scorecard, as effected in May 2015³³ through the codes of good practice, scores a firm on black economic empowerment under five elements:
- i) ownership;
 - ii) management control;
 - iii) skills development;
 - iv) enterprise and supplier development; and
 - v) socio-economic development.
- 13.3 There are 9 levels of B-BBEE status, from non-compliant, below level eight, to level one, the highest status.
- 13.4 In an attempt to contain the cost of compliance for small businesses and start-ups, there are carveouts in the codes for these enterprises, whereby they do not need a certificate from a verification agent to confirm their B-BBEE status.
- 13.5 Specifically, Exempted Micro-Enterprises (EMEs), with annual total revenue of R 10m (630k euros) or less, are deemed to have Level 4 status, irrespective of their ownership structure. Businesses within the first two years of their incorporation are treated as EMEs irrespective of turnover. There is a further classification for Qualifying Small Enterprises (QSEs), with turnover between R 10m (630k euros) and R 50m (3.16m euros). QSEs and EMEs can attain Level 1 and Level 2 status through 100% Black-ownership and 51% Black-ownership, respectively.
- 13.6 In addition to the generic scorecard, there are sector-specific scorecards. For example, in the financial services sector, tourism sector, and construction sector there are sector specific codes that supersede the generic scoring system for firms in these sectors. There are 12 sector codes in various stages of implementation, and there is no specific sector code for the health technology sector as of November 2019.
- 13.7 ‘New enterprise and supplier development’ is the element that carries the most weight in the generic scoring system, as of 2015. This has increased the importance of B-BBEE compliance even for businesses that do not wish to transact with the state directly. The reason is that if downstream businesses who are supplied by a firm wish to tender with the government, purchase a state-owned asset, or enter a public-private partnership, they will need to ensure that their own suppliers are

³² Werksmans Attorneys. (2018). B-BBEE Act and Codes Explained. Retrieved from <https://www.werksmans.com/wp-content/uploads/2018/11/BBBEE-Codes-Explained.pdf>

³³ Changes to the codes have been gazetted on 31 May 2019 and must be implemented by 30 November 2019.

B-BBEE compliant in order to attain a sufficient status to transact with any kind of government body.

- 13.8 Multinationals which wish to bypass the ownership requirements of B-BBEE must show that they have not conducted an ownership transaction elsewhere in the world. This qualifies them to score B-BBEE points by contributing to an Equity Equivalent Programme (EEP). The aim of the Equity Equivalent programme is to boost growth initiatives in South Africa.³⁴
- 13.9 EEPs may involve projects that support strategic economic development policies in South Africa, and can be approved by the Minister or form part of a sector specific B-BBEE code. The measures against which EEPs are measured are 25% of the value of the South African operations of the Multinational, or 4% of Total Revenue from its South African operations annually.
- 13.10 In accordance with the government's Preferential Procurement Regulations of 2017, for tenders with value below R 50m (3.16m euros), an 80/20 preference point system is applicable, with a weighting of 80 points based on the bid price, and 20 points based on the B-BBEE Status of the bidder. A similar system is applicable for tenders with value in excess of R 50m (3.16m euros), whereby a 90/10 preference point system is used. Points are allocated to the latter category in line with the bidder's B-BBEE status level, with maximum points awarded to Level 1 contributors, and none awarded for non-compliant contributors. Further, compulsory subcontracting to advance the objectives of B-BBEE is a requirement for tenders with value above R 30m (1.89m euros).
- 13.11 As noted above, EMEs and QSEs are exempted from having their B-BBEE level certified by an independent agency and can submit a sworn affidavit as proof of B-BBEE credentials. This incentivizes Dutch companies to either partner with a local distributor or establish a B-BBEE compliant operation in the country, in order to ensure that the highest possible score is attained in the tender process.

³⁴ BDO (2016) *Multinationals can participate in B-BBEE*. Accessible at <https://www.bdo.co.za/en-za/insights/2016/transformation/multinationals-can-participate-in-b-bbee>

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