



Sub-Saharan Africa: Healthcare Market Opportunities

Great Lakes St. Lawrence Governors and Premiers Africa Trade Office / October 2017

The Great Lakes St. Lawrence Governors and Premiers (GSGP) is a multi-governmental non-profit agency with members including the eight American states and two Canadian provinces in the Great Lakes / St. Lawrence region. The GSGP maintains an office in South Africa, with staff in other Africa countries, as part of its network of international offices designed to promote exports from the region.

Life Sciences, incorporating healthcare devices, instrumentation, consumables and services is a key strategic industry for the region. This paper describes the healthcare market in southern Africa, with emphasis on South Africa, to present the background for opportunities in the sector. Interested companies are welcome to further request individualized market services leading to specific country market research, agent/distributor research or other required key information. Contact details for the GSGP Africa office are located on the final page of this document.

South African Health Care Sector: Overview

Overall, the healthcare sector in sub-Saharan Africa continues to show signs of remarkable growth. The quality of hospitals and the availability of qualified doctors has dramatically improved over the last few years in much of the continent, although this growth is uneven. By making the transformation from traditional medicine to a modern and well-structured healthcare system, many African countries have been able to meet the growing demands for quality healthcare services for their people. Import-dependent medical equipment and supplies market tops US\$3.2 billion as African countries rely on imported medical equipment and supplies. Africa is a continent of over one billion people and South Africa is expected to account for US\$34.1 billion, equal to 29.1% of the total for healthcare for the population. With Egypt accounting for US\$12.7 billion or 10.9%. South Africa spends around US\$700 per person, while many countries considered less developed, spend less than US\$50 per person.

In South Africa, despite efforts to transform the health system into an integrated, comprehensive national health system, and significant investment and expenditure, the South African health sector has largely been beset by key challenges inclusive of: a complex, quadruple burden of diseases; serious concerns about the quality of public health care; an ineffective and inefficient health system; and spiraling private health care costs. The government GDP for healthcare is 8.7% of GDP (latest statistic 2013). South Africa is experiencing serious generalized HIV and TB epidemics. It continues to be home to the world's largest number of people living with HIV, estimated to be 6.4 million in 2012 (Spectrum policy modelling system, Statistics South Africa 2013). The country also ranks third among countries with the highest burden of TB in the world after India and China (WHO 2012). Levels of HIV and TB co-

infection are very high, with as many as 60% of patients having HIV-associated TB. There is also increasing incidence of multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB. The bulk of health-sector funding comes from the South Africa's National Treasury. The health budget for 2012/13 was R121-billion, which was aimed at improving hospitals and strengthening public health ahead of the National Health Insurance scheme.

Healthcare in South Africa varies from the most basic primary health care, offered free by the state, to highly specialized, hi-tech health services available in both the public and private sector. However, the public sector is stretched and under-resourced in places. While the state contributes about 40% of all expenditure on health, the public health sector is under pressure to deliver services to about 80% of the population – although with 47.9% of total healthcare expenditures. The private sector, on the other hand, is run largely on commercial lines and caters to middle- and high-income earners who tend to be members of medical schemes. While 81% of private expenditure comes from private health insurance plans, 14% are out-of-pocket private expenditures. The private sector also attracts most of the country's health professionals. This two-tiered system is inaccessible to a large portion of South Africans, but institutionally the public sector have suffered poor management, underfunding and deteriorating infrastructure. While access has improved, the quality of health care has fallen to some extent.

The Council for Health Services Accreditation for Southern Africa (COHASA) has been accrediting many hospitals under its jurisdiction that meet the applicable predetermined and published standards. However, Africa's healthcare industry is characterized by a huge division between the private and public sectors both in terms of facilities and funding. Perhaps the biggest problem facing the public sector currently is the rising incidence of HIV/AIDS, which is and will continue to place considerable strain on the public health system in many African countries. As a result, there exist immense opportunities for the supply of a wide range of hospital equipment, instrumentation, machinery and allied medical products. Being a price-sensitive market, African buyers are always on the lookout for high quality, competitively priced goods to meet their requirements.

South Africa is Africa's market leader in providing medical tourism services. In the five years from 2006 to 2010, more than 2.5 million medical tourists visited South Africa, out of which less than 10% were from high-income countries and more than 85% from other African countries, mostly from neighboring Lesotho, Swaziland, Mozambique and Zimbabwe. Like outbound tourists from Nigeria, visitors to South Africa tend to be middle-class or wealthy Africans. The other major medical tourism markets in Africa are in Egypt and Tunisia where people from the United States, Middle East and Europe access services at prices which are 60-70% lower than nearby European countries. In addition to a manpower shortage, the required infrastructure and medical equipment to treat conditions that often get referred abroad are not available in many African countries. There is little confidence in the domestic health system, even when the system can properly handle the condition. This is made worse by low public spending on health care and infrastructure in many African countries. For example, by 2011, only Rwanda and South Africa had met the 2001 Abuja Declaration in which African governments agreed to allocate at least 15% of their annual budgets to the health sector. In comparison, Nigeria allocated only 5.7% of the 2014 national budget to the health sector.

South Africa's healthcare expenditure has more than doubled in recent years, offering valuable market opportunities. Preliminary research indicates that there are a greater number of companies and NGOs

operating in the medical software arena (mobile/electronic health) in South Africa than in the medical device space. Given South Africa's well established telecommunications industry, the dichotomy that exists between public and private healthcare sectors, and the unregulated medical device arena, we expect global mobile trends to be even more pronounced.

Medical Equipment / Instrumentation

South Africa does not have a comprehensive system of medical device regulation similar to US FDA or European requirements. This lack of regulation and quality control measures contributes to the fact that imported products constitute an unprecedented 95% of all medical devices. It is unlikely that regulations will be implemented within the next 3 years. However, the market is very sophisticated and it is strongly advisable that the product be approved in another foreign market, or even better, carry the CE marque or be FDA approved. The exception is for electromagnetic medical devices (or radiation emitting devices), which must be registered with the Department of Health, and must have the CE marque. The national Department of Health is currently in the process of drafting the necessary policy documents and has indicated that these may become available in the future. The American Chamber of Commerce in South Africa (of which GSGP is an associate member through its contractor) track the progress of this device regulatory environment closely, as regulation will inevitably come.

Headline Industry Forecasts in 2013, the South African medical device market was estimated at US\$1.2bn, equal to US\$24 per capita (at April 2013 exchange rates). The market is forecast to grow in 2018 at a Compound Annual Growth Rate (CAGR) of 7.7%, which is average for the region. Medical device imports supply over 90% of the market, with a small amount of locally made devices making up the remainder. Between 2007 and 2012, medical device imports grew at a US dollar CAGR of 5.7%, but growth in 2013 was negative due to the weakness of the rand, this has improved significantly and by 2016 growth was higher. Between 2007 and 2012, medical device exports grew at a US dollar CAGR of 3.9%, but have seen much stronger growth in more recent years. The balance of trade deficit has fallen back below US\$1.0bn. Domestic production is estimated at around US\$200mn, of which more than half is exported, mainly to other African countries.

There are no special tariffs or restrictions reserved for used/refurbished equipment, as there is no distinction made between new and refurbished/used medical devices in customs regulations (comment current to 2016). No third party may legally import the same device in used/refurbished condition without the used device being subjected to new safety inspections, since each importer must obtain a license for each model that he/she imports. There are no restrictions on the number of licensed importers allowed per model currently. Duties are not payable on most medical and laboratory equipment (our office will be pleased to check for qualified GSGP companies). Some, such as blood sample collection tubes may carry a Most Favoured Nation (MFN) or Standard duty calculated at 10% of the value, and duties may be payable on certain plastics and disposables, but this is not applicable to EU exporters.

All public procurements are subject to the Public Procurement Law No: 4734-4735 and the related directives, which establish the principles and procedures to be applied in procurements held by all public entities and institutions governed by public law or under public control or using public funds. For detailed information please visit. All importers of medical devices must apply for a license in terms

of Section 4 (1)(b) of the Hazardous Substances Act, 1973 (Act 15 of 1973) found in South Africa's DOH Directorate: Radiation Control. Importers have to apply for a license for each medical device and must supply extensive information, including a completed 41BM-1 application form, which is again obtainable from the Radiation Directorate.

Distribution and sales

Typically, distribution is done through local agents and distributors. In South Africa, there is a legal distinction between an agent and a distributor. The agent orders the product on ad-hoc basis and generally works on a commission basis. The distributor will usually have a larger stocking capacity and enters into a formal agreement with the manufacturer/supplier. Some will only carry a specific brand name and become a subsidiary, e.g. Bayer (Pty) Ltd South Africa. Others may carry a string of non-competing products from different manufacturers. Most potential distributors with a national sales territory will prefer to have exclusive arrangements with the original manufacturer/supplier. It is important to ensure that local distributors have maintenance and after-sales repair capabilities, and train staff regularly.

Importers of medical devices are required to be registered license holders in order to do so, although the devices themselves are not currently required to be regulated as indicated above.

The sale of used equipment locally is not regulated. Public health institutions generally do not purchase refurbished/used medical equipment due to tendering conditions and/or internal hospital policy. However, there is no law prohibiting them from doing so. Single use or disposable devices are being reprocessed and reused by health practitioners, and is frequently done so in both private and public hospitals.

The long term growth prospects of the South African medical device market will be strongly influenced by the ANC government's policies in regards to the new National Health Insurance (NHI) scheme, the promotion of public-private partnerships to develop and upgrade hospitals, the serious shortage of healthcare personnel and an urgent need to effectively address the AIDS crisis in the country. A public private partnership has been signed with 23 companies to provide extra annual funding of ZAR40mn (US \$4.4mn) to support the training of medical students, develop management expertise among health professionals and fund local research in HIV/AIDS and TB over the next three years. Overall, the sub-Saharan market is seeing tremendous growth at this point in time.

Hospital sector

South Africa spends around 8.7% of its GDP on healthcare, amounting to about R127 billion. Of that amount, 47% is spent on the public sector which caters to 86% of the population, while 53% is spent on the private sectors which caters to about 14% of the population. Another disparity between the public and private healthcare sectors is that there are just over 4,500 doctors working in the public sector, whereas there are about 8,000 in the private sector. These disparities mean that majority of the South African population has access to over-stretched and strained healthcare, while those who can afford it can enjoy world-class healthcare services.

There are currently more than 3800 public health facilities, including 400 public hospitals, which have over 48 000 beds in South Africa. There are around 314 private hospitals and day clinics which have over 34 000 beds in South Africa. The public sector suffers from a shortage of doctors and of nurses. Many nurses emigrate and many doctors prefer to work for the private sector. A challenge facing foreign doctors who wish to work in South Africa is the cumbersome and inefficient bureaucracy. Most procurement for public hospitals is handled through the Department of Health.

The main private hospital groups in South Africa are Life Healthcare, Mediclinic and Netcare. Private hospitals are mainly found in the main metropolitan areas, with Gauteng having the largest presence. The main customers of the private hospitals are the medical aid members, while others are out-of-pocket payers and foreign patients. Most hospitals are classified as short-stay hospitals (30 days or less) and the average size of private hospitals is small containing under 200 beds. Medi-Clinic has 49 hospitals, and 7,600 beds, across the country. Another 3 hospitals are based in Namibia. Life Healthcare owns 64 hospitals, primarily in South Africa but more are planned in the southern Africa region. Netcare is expanding vigorously in the region outside of South Africa with 116 hospitals and 90 primary healthcare centers, inclusive of over 13,000 hospital beds. All of these private companies are profitable, and generally expanding inside and outside South Africa. Medi-Clinic has interests in the United Arab Emirates, while Netcare has interests in the United Kingdom. There are a number of independent hospitals and small groups that make up the remainder of the private hospital statistics.

Statutory health insurance - National Health Insurance

The South African Department of Health announced its plan to implement the National Health Insurance (NHI) in South Africa. The NHI is intended to bring about reform that will improve service provision and health care delivery. It aims to promote equity and efficiency to ensure that all South Africans have access to affordable, quality health care services regardless of their employment status and ability to make a direct monetary contribution to the NHI Fund. The NHI is being phased in over 14 years, beginning in 2012. In 2012/13, the government earmarked R1-billion to its pilot projects. By 2017, the NHI had seen little progress as there would be an additional US\$25 billion, likely more, added to the national fiscus in order to implement the plan. South Africa's income tax base is generally very narrow, with only 6 million contributors, and the additional tax burden would have to be located from some other quarter.

In order to facilitate the implementation of the NHI, the Department of Health is following the "10-point plan", which is a strategic programme to improve hospital infrastructure and human resources management, as well as procurement of necessary skills and equipment. Under this plan, health facilities – such as nursing colleges and tertiary hospitals – are being upgraded and rebuilt to lay the way for the implementation of the NHI scheme. Apart from infrastructure and management overhauls, another factor for ensuring the success of the NHI will be the strict regulation of the sector to make it more affordable to all South Africans.

Resources:

National Health Insurance: www.nhisa.co.za

Private medical aid

There are around 100 medical aid schemes operating in South Africa. The medical aid beneficiaries are largely concentrated in the metropolitan areas, with Gauteng having the largest concentration. There are over 7 million medical aid beneficiaries in the country. The body which provides regulatory supervision of private health financing through medical schemes is the [Council for Medical Schemes](#).

Opportunities:

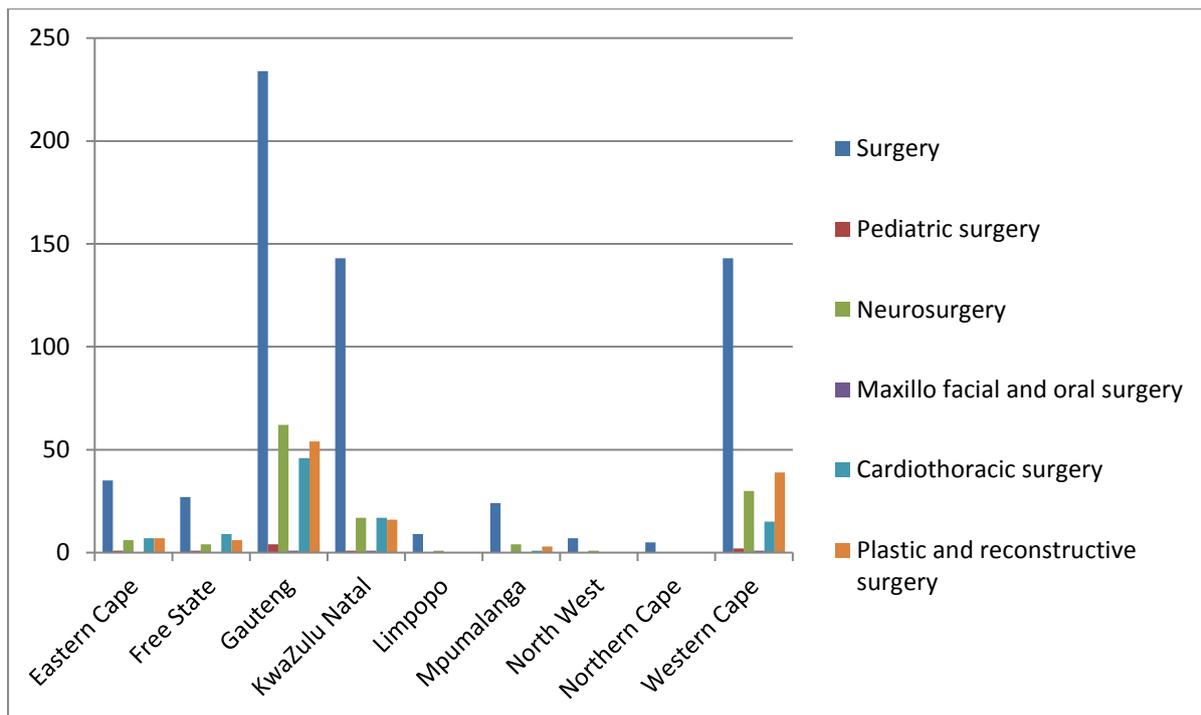
- There is a potential gap in this market related to the degree to which a product can be customised to meet an individual's unique needs.

Private medical aid providers

Discovery Health	www.discovery.co.za
Bonitas Medical Fund	www.bonitas.co.za
Fedhealth	www.fedhealth.co.za
Genesis	www.genesismedical.co.za
Momentum	www.momentum.co.za
Ingwe (part of Momentum)	www.ingwehealth.co.za
Liberty	www.libertyhealth.co.za
Medshield	www.medshield.co.za
Metropolitan	www.metromed.co.za
BestMed	www.bestmed.co.za
Resolution Health	www.resomed.co.za
Commed	www.commed.co.za
Keyhealth	www.keyhealthmedical.co.za
Medihelp	www.medihelp.co.za
Profmed	www.profmed.co.za
Sizwe Health	www.sizwehealth.com
Spectramed	www.spectramed.co.za
Topmed	www.topmed.co.za

Doctor's Surgeries

Surgeons are concentrated heavily in Gauteng province, followed by Kwazulu Natal and Cape Town. See graph below for geographic and field distribution of registered surgeons.



South Africa is known for some of the surgical achievements performed in the country. The first heart transplant took place in Cape Town in 1967 by Dr Chris Barnard. Cardiac surgery in all its forms is practiced across South Africa at state hospitals as well as the many private hospitals and clinics around the country. Heart surgery in South Africa continues to attract patients from all over the world, seeking out first-class medical facilities and specialized skills. Of course, the fact that South Africa is a value-for-money destination is also a major draw card. Of more recent, the first successful penis transplant took place earlier in 2015 at the Tygerberg Hospital.

Robotic surgery is also present in the country. The Urology Hospital unveiled the first robotic surgery system in the country in late 2013.

There is a rising demand in South Africa for plastic surgery (as can be seen from the high number of plastic surgeons in comparison with other types of surgeons). This demand is driven both locally and by Sub-Saharan foreign patients. The most popular procedures for the African clients are breast reductions, liposuctions and tummy tucks.

Resources:

Health Professions Council of South Africa: www.hpcsa.co.za

The Association of Surgeons of South Africa: www.assa.co.za

Pharmacy sector

South Africa has the best developed pharmaceutical industry in Sub-Saharan Africa and is a fast-emerging pharmaceutical market. In 2014, the pharmaceutical market was valued at US\$3.67 billion and was projected to keep growing at about 6% from 2014 until 2018. The industry comprises of a complex network of manufacturers, distributors and dispensers. Generics comprise approximately

60% of allocated market share by volume, and 33% of market value in 2016. As with the healthcare sector, the pharmaceutical sector is also a two-tier sector. The public sector is characterized by high-demand and low-prices, whereas the private sector prices are comparable to those in developed countries.

The government, with view of rolling out its National Health Insurance plan and making pharmaceuticals more affordable, aims to increase the production and distribution of generic drugs. Currently, generics account for about 60% of the market in terms of volume, but about one-third in terms of value. The government procures large volumes of drugs via tenders. The private demand for generic drugs has also been growing.

Some of the largest South African manufacturers are Adcock Ingram, Litha Healthcare and Aspen Pharmacare. In addition to the local manufacturers, there are a number of multinationals that have a presence in South Africa and from where they operate their regional activities. Some of the multinationals present are: Sanofi, Johnson and Johnson, GlaxoSmithKline and Pfizer.

South Africa is the biggest market for anti-retrovirals. South Africa announced in late 2014 that it would spend USD 2.2 billion on HIV/AIDS drugs for public hospitals over the next two years and that it would purchase two thirds of those from local manufacturers. In 2014, there were 2.5 million people who were taking ARVs – a steep rise from 2011 when it was just over 101 000 people.

Opportunities:

- Meeting fast-growing public sector demand for pharmaceuticals, especially (i) ARVs (demand projected to increase from the current 2.2 million to 3.7 million patients in 2016-2017); (ii) anti-TB medicines; and (iii) medicines for non-communicable diseases/conditions such as diabetes, cancer, circulatory and cardiovascular conditions etc, will require more investment in the sector.
- Manufacturing generic copies of medicines losing patent protection in 2014-2015 for supply into the SA public and private health sectors offers massive investment opportunities for new entries in the sector.
- There is a lack of innovative pharmaceutical products in the South African market, as well as more innovative pricing structures, presenting an opportunity for manufacturers/suppliers of such.

Biotech sector

During the apartheid era and South Africa's isolation, the country developed scientific and technological capabilities, especially in arms, mining and textile industries. This scientific base is now being used in other areas, including biotechnology. Government support of health biotechnology has been growing, and in 2000 it began focusing its research support to biotechnology. This led to the adoption of the 2001 National Biotech Strategy for South Africa, a policy framework to create incentives for the biotechnology sector. Within this framework, biotechnology is identified as potentially contributing to national priorities of access and affordability of health care, food security, job creation and environmental protection.

Public research institutes, laboratories and universities are key players in South Africa's health biotechnology development. The government has two main research institutions doing health biotechnology R&D, the Council for Scientific and Industrial Research (CSIR, Pretoria) and the MRC, the latter of which is of particular interest because it specifically targets health research.

South Africa's entry into the modern health biotechnology industry is recent and, therefore, most of the companies have a short list of novel bioproducts for health biotechnology. Their portfolios generally consist of biogenerics, licensed products from foreign companies or products still in the pipeline.

Experts say that there is a huge potential for the South African biotechnology industry. There are strong research scientists, government research councils, a traditional research system, and biodiversity. The large burden of disease of infectious diseases has meant that biotech has focused a lot on tackling that issue.

Other Sectors

While this document cannot cover the many sectors needed in Africa, nor the amount of requirements filled by exporters of goods and services our office notes that the following sectors are worth mentioning:

Education toward professional training of physicians and registered nurses
Frail care / step-down facilities management, design and requirements
Hospital and clinic specialized medical furniture
IT in medical management solutions
Specialty consumables

Other sectors may be summarized as required for Great Lakes and St. Lawrence regional companies.

Summary

The Sub-Saharan Africa region holds a wealth of opportunity for companies across a range of sectors in the healthcare industry. Our team is able to assist with firms entering the market, making contact with buyers and potential partners and assisting with opportunities as they exist. We welcome your contact with us in this market toward the creation of export sales.

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