GDP per capita

USD 6,609

Second-largest economy in Africa, 34th-largest in the world

Parliamentary Representative

DEMOCRATIC REPUBLIC

South Africa consists of **9 PROVINCES**, each with its own Legislature, Premier and Executive Council

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Sweeping Changes in South African Healthcare

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Since first free elections in 1994, many were the efforts made by South African governments to combat health inequalities. As the government moves ahead with plans to implement mandatory national insurance to find solutions to universal, sustainable and effective healthcare services there are still extreme differences and disparities and a magnitude of challenges to face.

Total GDP (nominal)
386 billion USD
(2019 estimate, IMF)

The African National Congress (ANC) is the governing political party. Ruling party of post-apartheid South Africa since the election of Nelson Mandela in 1994, winning every election since then

Cyril Ramaphosa, President of South Africa serves both as head of state and as head of government, since 2017

Along with Egypt, South Africa accounts for 40% of the medical devices market in Africa

Member of the World Trade Organization (WTO), the G20 and BRICS (Brazil, Russia, India, China, and South Africa).

**South Africa is well integrated into regional economic infrastructure as formalized by Membership in the Southern African Development Community (SADC).
In addition, the Southern African Customs Union (SACU) agreement with Botswana, Namibia, Lesotho, and Swaziland facilitates commercial exchanges.**

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The Republic of South Africa, with a population of 57.3 million, is located at the southern tip of the continent and is one of Africa's most economically developed countries with the highest degree of modernization. Its executive capital is Pretoria, though Bloemfontein is its judicial capital and Cape Town is the legislative capital. The largest city is Johannesburg. A long history of political shifts and changes has made it one of the most multi-ethnic and multicultural nations. The constitution of South Africa recognizes 11 official languages, the fourth highest number on Earth.

The Republic of South Africa is also known as the "Golden Kingdom" because of its gold reserves, but it also produces platinum, manganese, vanadium and titanium. **Mining, manufacturing and agriculture are the three pillars of the economy. Gold mining, drilling equipment, rail manufacturing, automobile assembly and cardiac surgery are among the best in the world.** In addition, iron and steel, machinery, electrical goods, chemicals, food and other industries are also prolific. The tourism sector in 2017 experienced 12.8% growth, well above the global average of 8%.

Beyond the elimination of legislated racial policies, advances in South Africa over the past 20 years include substantial economic growth, an expansion of the black African middle class as well as enormous social progress, by bringing to millions of citizens access to key public services, such as education, health, housing and electricity. **An ambitious policy of redistributive grants has also been put in place, lifting a large share of the population out of poverty even if poverty rate, at about a third of the population, remains high compared to many emerging economies.** Social grants have reduced absolute poverty, but 45% of the population still lives on approximately $2 per day (the upper limit for the definition of poverty). More than 10 million people live on less than $1 per day.

Its legal framework is well regarded, and its judiciary is perceived as independent. The advanced banking system and deep financial markets have made South Africa a regional hub for financial services. The Johannesburg Stock Exchange (JSE) ranks among the top emerging market exchanges in the world. Nevertheless, growth has trended down markedly recently due to constraints on the supply side. Low growth has led to the stagnation of GDP per capita, and persistent high unemployment and inequalities. The economy faces many structural challenges while high inflation limits room for monetary policy support and high public debt constrains public spending.

Many doctors prefer to work at private clinics or abroad, since public clinics do not pay well and imply difficult general conditions.

Healthcare Context

Healthcare services and products in South Africa are provided by parallel running public and private healthcare systems. **The public system serves most of the population (80%) through government-run public clinics and hospitals, the wealthiest 17-20% of the population use the private system and are far better served.** The private health sector provides health services through individual practitioners who run private surgeries or through private hospitals, which tend to be in urban areas. The public health services are divided into primary, secondary and tertiary through health facilities located in and managed by the provincial departments of health. The provincial departments are thus the direct employers of the health workforce while the National Ministry of Health is responsible for policy development and coordination.

The Bill of Rights in Section 27 of the Constitution of the Republic of South Africa of 1996 states unequivocally that access to healthcare is a basic human right. It guarantees everyone *"access to health care services"* and states that *"no one may be refused emergency medical treatment."* Hence, all South African residents, including refugees and asylum seekers, are entitled to access free basic medical care. Thus, everyone can access both public and private health services, with access to private health services depending on an individual's ability to pay. **South Africa spends on average 8.4%-8.8% of its GDP on healthcare, or around US$437 per capita. Of that, approximately 42% is government expenditure while, a disproportionate 52% comes from private expenditure, even though private healthcare is only available to a very small section of the South African society (around 17.1%).**

Most patients access health services through the public sector District Health System, which is the preferred government mechanism for health provision within a primary healthcare approach. There are more than 400 public hospitals and more than 200 private hospitals. The provincial health departments manage the larger regional hospitals directly. Smaller hospitals and primary care clinics are managed at district level. The national Department of Health manages the 10 major teaching hospitals directly. The Chris Hani Baragwanath Hospital is the third largest hospital in the world (3,400 beds) and it is located in Johannesburg. **Due to its chronically underfunded system, public hospitals and clinics are often lacking modern equipment and especially personnel.** Many doctors prefer to work at private clinics or abroad, since public clinics do not pay well and imply difficult general conditions. According to the General Household Survey 2017, conducted by Stats SA, the national statistical service of South Africa, about seven out of every 10 (71.2%) households used public-health facilities as their first point of access when household members needed healthcare services for an illness or injury. **In view of the introduction of the National Health Insurance (NHI) plan and as part of an effort to broaden access to treatment in a country where about 80% of the population lacks private insurance, the Government is maintaining, constructing or revitalizing the 872 primary healthcare (PHC) facilities available.** Also, at the end of March 2018, a cumulative total of 1,507 of the

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In recent years, permission for senior full-time staff in the public sector to spend a limited proportion of their time working in the private sector has further diluted their public-service activities,leaving many people relying on a public system with too few doctors.

3,434 public health facilities assessed had attained Ideal Clinic status, which is an initiative that was started in July 2013 to improve quality and efficiency in PHC facilities in the public sector.

Although some of the provinces in South Africa contain large cities, the bulk of the population lives in rural communities (about 64.7%), which are however only staffed by some 30% of the doctors available and with only 3% of newly qualified doctors taking jobs there. The remaining 70% of doctors work full-time in the private. In recent years, permission for senior full-time staff in the public sector to spend a limited proportion of their time working in the private sector has further diluted their public-service activities, leaving many people relying on a public system with too few doctors.

In 2013, it was estimated that vacancy rates for doctors were 56% and for nurses 46%. South Africa has a total of 23 universities and 9 schools of health sciences. In addition, there are 9 provincial nursing colleges and several private nursing schools. Collectively, the medical schools have an annual output of medical graduates ranging between 1,200 and 1,300. This is viewed as grossly inadequate for a country with a population size of over 57 million. **There is realization by the Government that the health workforce plays a critical role in advancing the health system goals, largely driven by a policy position of improving access to healthcare for all citizens.** In line with South Africa's strategic objective to increase the production of human resources for health is the training of doctors in Cuba as part of bilateral agreements on public health between South Africa and Cuba signed in 1994, the Nelson Mandela/Fidel Castro Medical Collaboration Program initiated to relieve the acute shortage of human capacity in the public health sector. The Health Professions Council of South Africa (HPCSA), maintains a register of all medical doctors that are licensed to practice medicine in South Africa. **As of October 2018, there were 46,091 medical practitioners on the Medical and Dental Board register. This figure includes those in the medical profession who are specialists**. In line with the sentiments of #feesmustfall protesters who in 2015 sparked a nationwide revolt against high university fees as a barrier for deserving poor students, the Government's policy to fully subsidized higher education and training for poor and working-class students will further ensure access to more students to enroll in health studies.

Public sector people-to-doctor ratio, 2015 – 4,024 to 1

Public sector people-to-nurse ratio, 2015 - 807 to 1

Hospital beds 2.3 per 1000 inhabitants (OCSE, 2010)

The public sector uses a Uniform Patient Fee Schedule (UPFS) as a guide to billing for services by grouping patients into three categories defined in general terms, which include: full paying patients—patients who are either being treated by a private practitioner, who are externally funded, or who are some types of non-South African citizens—, fully subsidized patients—patients who are referred to a hospital by Primary Healthcare Services— and partially subsidized patients—patients whose costs are partially covered based on their income. There are also specified occasions in which services are free of cost.

Following the end of the Second World War, South Africa saw a rapid growth in the coverage of private medical provision, with this development mainly benefiting the predominantly middle-class white population. Membership of health insurance schemes became effectively compulsory, being such membership a condition of employment, together with the fact that virtually all whites were formally employed. **According to Stats SA's General Household Survey 2017, by September 2018, there were about 80 medical schemes in South Africa with over 8 million beneficiaries, representing a relatively small percentage of individuals belonging to a medical aid scheme.** Despite policy initiatives aimed at structuring affordable low-cost healthcare funding products, medical schemes have remained unaffordable to the majority of South Africans over the years, with scheme contributions by members increasing at an alarming pace and out-of-pocket (OOP) expenses by members showing double digit growth. According to the Council of Medical Schemes a third (33%) of total OOP expenditure is spent on medicine, meaning patients spend around R9 billion rand out of their pockets on medicine alone. OOP also constitutes a large proportion (18.6%) of total healthcare expenditure for individuals who were already making significant premium con-

tributions to medical schemes. While up to 25% of uninsured people pay out-of-pocket for private-sector care.

Since coming to power in 1994, the African National Congress (ANC) has implemented a number of measures to combat health inequalities in South Africa. These have included the introduction of free healthcare in 1994 for all children under the age of six together with pregnant and breastfeeding women making use of public sector health facilities (extended to all those using primary level public sector healthcare services in 1996) and the extension of free hospital care (in 2003) to children older than six with moderate and severe disabilities. **Furthermore, a National Health Insurance (NHI) initiative, aiming at eradicating financial barriers to healthcare access is now in a pilot phase prior to being implemented across the country in a phased approach from 2016 – 2025. The NHI system aims to ensure universal health coverage for all citizens and residents of South Africa, irrespective of socioeconomic status, to have access to good-quality, affordable health services.**
The NHI is speculated to propose that there be a single National Health Insurance Fund (NHIF) for health insurance that would buy services from accredited public and private facilities, which would then provide care for registered members. This fund is expected to draw its revenue from general taxes and some sort of health insurance contribution. Currently, most healthcare funds come from individual contributions coming from upper class patients paying directly for healthcare in the private sector. There is in fact a discrepancy between money spent in the private sector which serves the wealthy (about US$1,500 per head per year) and that spent in the public sector (about US$150 per head per year) which serves about 84% of the population. The NHI proposes that healthcare fund revenues be shifted from these individual contributions to a general tax revenue. Because the NHI aims to provide free healthcare to all South Africans, the new system is expected to bring an end to the financial burden facing public sector patients. The National Development Plan (NDP), appointed by former President Jacob Zuma in 2010, aiming to eliminate poverty and reduce inequality by 2030, expects South Africa to have, among other things, raised the life expectancy of South Africans to at least 70 years; produced a generation of under-20s that is largely free of HIV; achieved an infant mortality rate of less than 20 deaths per thousand live births, including an under-five mortality rate of less than 30 per thousand; achieved a significant shift in equity, efficiency and quality of health service provision. **Yet, disparities in South Africa are amongst the widest in the world. The persistence of such disparities is incompatible with improvements in population health and are associated with diseases of poverty such as HIV/AIDS and tuberculosis.** The top 10% of South Africans earn 58% of the total annual national income, whereas the bottom 70% combined earn a mere 17%.
South Africa, with 0.7% of the world's population, accounts for 17% of the global burden of human immunodeficiency virus (HIV) infection, continuing to be home to the world's largest number of people living with HIV. In 2003, after much government denial and slow response regarding funding for HIV and the acquired immunodeficiency syndrome (AIDS), considerable local and international pressure resulted in the government introducing an ambitious program to provide antiretroviral (ARV) therapy to patients with HIV infection. Access to ARV treatment through the public sector has changed historical patterns of mortality as the number of AIDS-related deaths has declined consistently since 2007. **Nonetheless, according to Stats SA, the total number of persons living with HIV has increased from an estimated 4.25 million in 2002 to 7.52 million by 2018.** An estimated 13.1% of the total population is HIV positive. Driven in recent decades by the spread of HIV infection, the incidence of tuberculosis has also increased from 300 per 100,000 people in the early 1990s to more than 950 per 100,000 in 2012. Despite notable progress in improving treatment outcomes for new smear-positive tuberculosis cases, the tuberculosis burden remains enormous.

2018 HEALTH INDICATORS

Life expectancy at birth, 61.1 years for males and 67.3 years for females

Infant mortality rate per 1 000 live births – 36.4

Under-five mortality rate per 1 000 live births – 45.0

Source: South African Government (Stats SA), https://www.gov.za/about-sa/health

Registered Persons, HPCSA, October 2018	
Dental Assistants	4,908
Student Dental Assistants	1,949
Oral Hygienists	1,226
Student Oral Hygienists	400
Dental Therapists	743
Student Dental Therapists	282
Dentists	6,466
Student Dentists	1,158
Medical Practitioners	46,091
Medical Students	13,158

Source: HPCSA, https://www.hpcsa.co.za/Publications/Statistics

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Oral Healthcare

The oral healthcare system very much reflects general health. **The richest part of the population is privately insured, and oral care is comparable to the European standards but the majority of South Africans have no access to private services and are dependent on the government for oral healthcare; but just around 10% of the population uses public oral health services.** This underutilization is due to limited resources and inaccessibility. Consequently, oral diseases are widespread and affect large numbers of people in terms of pain, tooth loss, disfigurement, loss of function.

There are 6,466 dentists including 481 dental specialists registered within the Health Professions Council of South Africa (HPCSA). Dental specialists are mostly divided into maxillo-facial surgeons (30%), orthodontists (30%) and prosthodontists (17%). The number of dentists has increased at around 2% per annum and most dentists and dental specialists reside in the most metropolitan provinces of South Africa. In the past decade, the number of female dentists has almost doubled, and the number of Colored, Black and Asian/Indian dentists and dental specialists has increased sharply, which could be a result of increased admission of previously disadvantaged students to dental schools. Only one in six registered dentists works in the public sector. **There are fewer than 2.5 dentists per 100 000 people in the country. The situation is even more complicated when it comes to dental specialists, with only 160 in the public sector in the entire country. This translates into fewer than half a specialist (0.4) per 100 000 people.**

Number of Dental Practices by Province

Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	Northern Cape	North West	Western cape	**TOTAL**
298	209	2,322	924	361	276	72	233	1,099	**5,794**

Source: https://www.medpages.co.za/sf/index.php?page=stats&countryid=1. Medpages Database. Both public and private practitioners are included, though private sector data is more complete than public sector (Medpages database is not the official statistics institution)

DENTAL SCHOOLS

- Cape Peninsula University of Technology
The Faculty of Health and Wellness Sciences
www.cput.ac.za/academic/faculties/healthwellness/departments

- Durban University of Technology -
The Department of Dental Sciences
www.dut.ac.za/faculty/health_sciences/dental_sciences

- Sefako Makgatho Health Scienes University
www.smu.ac.za

- University of Pretoria - Faculty of Health and Sciences
www.up.ac.za/school-of-dentistry

- University of the Western Cape
www.uwc.ac.za/Students/Admin/adminreq/Pages/Faculty-of-Dentistry.aspx

- University of the Witwatersrand, Johannesburg
www.wits.ac.za/course-finder/undergraduate/health/dental-science

The Competition Commission is a statutory body constituted in terms of the Competition Act, No 89 of 1998 by the Government of South Africa empowered to investigate, control and evaluate restrictive business practices, abuse of dominant positions and mergers in order to achieve equity and efficiency in South Africa in order to:

- Promote the efficiency, adaptability and development of the economy;
- Provide consumers with competitive prices and product choices;
- Promote employment and advance the social and economic welfare of South Africans;
- Expand opportunities for South African participation in world markets and recognise the role of foreign competition in the Republic;
- Ensure that small- and medium-sized enterprises have an equitable opportunity to participate in the economy; and
- Promote a greater spread of ownership, in particular to increase the ownership stakes of historically disadvantaged persons.

www.compcom.co.za

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With more than 90% of South African dentists working in the private sector, treating only 17-20% of the population (those covered by some form of private health insurance), most South Africans look to the public sector for their healthcare needs; a public sector under immense pressure and ill-equipped. Consequently, public health dentists focus largely on extraction rather than any restorative procedures or prevention.

Due to the general lack of oral health facilities and workforce, exacerbated by an unequal distribution of dental services in the country, oral health disparities continue to widen, more so amongst the disadvantaged and vulnerable groups. To escalate matters further, the high burden of infectious diseases such as HIV and TB faced by the country impacts upon budgetary priorities reducing the availability of funding for oral health matters.

There are currently no oral health surveillance data being collected on a regular basis besides that of services provided. There are few school-based oral health programs in the country and regrettably, there is no monitoring and evaluation. These factors raise questions with regards to the reliability of what is now known about the state of oral health in the country. The last available National Oral Health Survey seems to have been conducted well over a decade ago (1999-2002). The results showed a general reduction in dental caries severity of the permanent dentition of 12-year-old children; they however also revealed that the greatest need for the treatment of dental caries in South African children was for preventive services, restorations and extractions. **Approximately 60% of primary school children suffered from dental decay and, more concerning, over 80% of these children remained untreated due to the overburdened oral health system and poor health seeking behavior.** Oral health needs vary widely from province to province. The greatest need was recorded in the Western Cape, where almost 80% of children needed oral healthcare and the lowest need in Limpopo province. It was further indicated that 32% of children required orthodontic treatment because of premature dental extractions. A considerable majority of adolescents and adults presented with gingivitis and periodontal diseases. With the high prevalence of HIV/AIDS, many of the infected patients also suffer oral HIV-associated lesions. The Dental Aesthetic Index was used to assess the prevalence of malocclusion and 32.3% of 12-year-old children needed definitive orthodontic treatment.

NATIONAL ORAL HEALTH SURVEY (1999-2002)

- **Caries free, 6-year-olds - 39.7%**
- **DMFT, 12-year-old group - 1.1 (from 2.5 in 1982)**
- **Children with signs of dental fluorosis - 20.2%**

According to a research by Oral-B in 2014 (survey of 1,000 male and female South Africans who live in South Africa and are the primary oral care shoppers, aged 18+), in which the vast majority of South Africans say that their oral health is important to them, 42% had not seen a dentist in the 12 months before being surveyed. About half of those who did visit a dentist also highlighted that they only did so because of a specific problem and not because it was time for a general check-up. High levels of oral diseases and curative treatment is economically draining for a country like South Africa, resulting in a greater need for highly skilled oral health professionals, expensive equipment, oral health facilities and the necessary financial resources. **An effective way to address these issues could be the need for a population-based system with a focus on prevention of oral disease and oral health promotion, as opposed to the existing curative-driven and individually focused system.**

Among the expertise, dental public health specialists, also known as community dentistry specialists, are particularly trained to work for the public to assess the dental needs of the population. They are not primarily clinical specialists but rather focus on the oral health status of the whole population as opposed to that of individuals. They are trained to plan appropriate evidence-based interventions and preventive programs, to formulate, supervise and evaluate oral health policies and strategies to benefit the whole population and to manage the oral health services of the country. While there are 36 of these professionals registered within the HPCSA, their skills seem to be largely underutilized in the public health system arena, most of them being employed in academia institutions, primarily due to lack of employment opportunities in the public sector.

Furthermore, the current number of oral health professionals in South Africa is not enough and there is shortage of adequately trained oral health professionals to meet oral health needs of the population in the public sector. Provinces such as Limpopo and Northern Cape have few oral hygienists employed in the public sector. This is of concern because preventive and/or promotive community oral health services are driven primarily by oral hygienists.

Ratio Per One Oral Health Professional to Population in 2010, by Province

Eastern Cape	Free State	Gauteng	KwaZulu-Natal	Limpopo	Mpumalanga	Northern Cape	North West	Western cape
30,514	19,214	6,217	15,540	32,967	15,797	20,070	14,957	5,167

Source: Lehohla PJ. Mid-year population estimates by province. Statistics South Africa. Statistics release [serial online]. (P0302); 2010:4 [cited 2012 May 19]. Available from: http://www.statssa.gov.za/publications/P0302/P03022011.pdf
Fisher R. Oral health professionals' statistics by provinces. The who, what & where of health care. Medpages Statistics [serial online]. 2010:1– 2 [cited 2012 Jun 20]. Available from: http://www.medpages.co.za

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About half of those who did visit a dentist also highlighted that they only did so because of a specific problem and not because it was time for a general check-up.

Even on the dental technology sphere, the current status quo regarding limited or non-existent accessibility to affordable services offered by dental technicians to ordinary South Africans is a real problem affecting millions of people, especially those from the previously disadvantaged background. In such a context, the proposed NHI becomes key. An increasingly-ageing population requires an efficient and more feasible prosthetic service, without compromising on standards, to meet the needs of the edentulous population in South Africa. **Within the framework of gloom economy is the difficulty for dental laboratory owners to employ graduates, or for graduates to set up their own dental laboratory. There is a mismatch between student graduate numbers and the graduates that enter and stay in the profession due to barriers in opening and running their own laboratories.** Furthermore, there is stiff competition, dominance and protectionist practices by established technicians. The concentration of technicians and technologists in urban areas further compounds the situation. On the positive side, however, is the Government's policy announcement to provide free tertiary education which will mean more students will enroll to pursue studies in dental technology. Up until now students, especially from disadvantaged backgrounds, had to either be funded through student loans (if they qualified) and had to endure harsh socio-economic conditions in universities.

REGISTERED DENTAL TECHNICIANS/ DENTAL

Year	Total Registered	New Registrations	Deregistered
2016/2017	1,121	36	86
2017/2018	1,040	7	2

Source: https://sadtc.org.za/education/

Race	Gender	Geographical Location
Black: 126 Colored: 79 Indian: 83 White: 747 Other: 5	Female: 256 Male: 784	Eastern Cape: 41 Free State: 34 Gauteng: 476 Kwa-Zulu Natal: 152 Limpopo: 22 Mpumalanga: 33 North West: 31 Northern Cape: 10 Western Cape: 238 Overseas: 3

Source: https://sadtc.org.za/education/

	2017/18	2016/17
Lab Owners (Dental Technicians/Technologists)	622	660
Lab Owners (Dentists)	51	51
Dental Traders	9	9
University Lecturers	15	14
CDP Providers (Continuing Professional Development)	24	24
Graduates (Techniciansand Technologists)	91	93

Source: https://sadtc.org.za/education/

REGISTRATION OF DENTAL LABORATORIES

Year	Total Registered	New Registrations	Deregistered
2017	641	24	35
2018	605	2	5

Source: https://sadtc.org.za/education/

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Dental technology practitioners that practice in the Republic must be registered within the South African Dental Technicians Council (SADTC). According to the Council, the breakdown of the racial and gender profile of registered practitioners and students within the profession remains largely skewed. Three universities in South Africa offer training for dental technicians/ technologists as well as dental assistants (Cape Peninsula University of Technology, Durban University of Technology, Tshwane University of Technology).

Medical and Dental Industry

Even if actual growth does not match that of other African economies, South Africa is the most advanced, diversified and productive economy in Africa, enjoying relative macro-economic stability and a largely pro-business environment. It is, for this, the primary business hub for the medical device industry in Sub-Saharan Africa as a substantial portion of medical device and lab equipment exports are sent to other parts of Africa.

Top Sub-Saharan Destinations for Medical Devices from South Africa, 2017

Country	USD Millions
Namibia	31.46
Botswana	18.85
Uganda	9.80
Swaziland	9.69
Zimbabwe	9.55
Zambia	5.90
Kenya	5.85
Mozambique	4.82
Lesotho	3.91
Malawi	3.47
Tanzania	3.29
Mauritius	2.64
Democratic Republic of Congo	2.23

Source: AFH19_Industry_Insights_Medical_Devices_Market_REPORT.pdf by Africa Health, an Informa Experience

Even if underdeveloped and considerably restrained by funding issues, poor infrastructure and staff shortages, particularly in the public sector, South Africa's health market offers potential for growth, also influenced by national legislation related to the implementation of government's National Health Insurance program. This combined with the Competition Commission's market inquiry into private healthcare costs and further changing legislation will effect radical change to the purchasing and provision of private and public healthcare in South Africa. Despite recent cutbacks, the government sector is still the major purchaser of healthcare equipment and supplies. Opportunities will exist for exporters of medical equipment, especially new and innovative equipment, as extensive upgrades and development of hospital infrastructure is being considered. Nonetheless, the best prospects for advanced technology and equipment remain in the private sector as very sophisticated and boasts world class facilities with several centers of excellence. The government's encouragement of public private partnerships in the development of hospitals is a new area of growth.

There is limited medical device production in South Africa and the market is largely dependent on imports (around 90%). Local firms tend to be small or medium sized businesses with less than 50 employees and often combine distribution activity with manufacturing. Multinational companies often operate in a joint venture capacity with local firms. Most South African manufacturers specialize on producing basic medical equipment and supplies. According to an "Africa Health" report by Informa, a leading international events, intelligence and scholarly research group, the output by the domestic medical manufacturing industry is estimated to be around USD 200mn-USD 300mn, of which more than half is exported. Production is focused on bandages and dressings, medical furniture and low technology items. The import market is dominated by the United States and Germany followed by China, Switzerland, the United Kingdom and Japan in all categories, but particularly in orthopedics, prosthetics, patient aids, other devices and consumables. Buyers are increasingly looking towards sourcing from Asian markets to save on costs. China is making significant inroads, increasing by around 10% in terms of market share. Consistent with healthcare infrastructure upgrades, the demand for diagnostic imaging equipment is forecast to grow approximately 12% between 2016 and 2021. **Although dental equipment represents the smallest product area (3.6% of all medical imports), it grew at a CAGR of 10.2% in the past year even if access to good dental health remains a problem for most of the population in the public sector.** Because of the high quality of dental care available in private settings and in combination with its general tourism appeal, South Africa has seen an increase in dental tourism industry. First class surgeons work to extremely high standards in clinics, offering procedures at a fraction of the cost of European and US centers. Cape Town and Johannesburg are particularly popular. People are in fact not just visiting for simple treatments like fillings, whitening, dentures and implants but many come seeking wisdom tooth extraction, cleft lip and palate surgery and even surgery for the replacement of damaged or lost bone.

South Africa Medical Device Market Value by Product Category, 2018

Devices	USD Millions
Consumables	241.00
Diagnostic Imaging	199.30
Orthopedics & Prosthetics	153.70
Patient Aids	156.00
Dental Products	41.30
Other Medical Devices	487.10
TOTAL	**1,278.40**

Source: AFH19_Industry_Insights_Medical_Devices_Market_REPORT.pdf

Regulations - The Department of Health has issued (2016) new regulatory requirements for medical and in vitro diagnostics (IVD) devices which will be overseen by a recently established regulatory authority, the South African Health Products Regulatory Authority (SAHPRA). This entity has adopted harmonization initiatives that will ultimately see an alignment of registration and product approval requirements with those of regulatory authorities in other regions.

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Also, the National Treasury published new revised Preferential Procurement Regulations in January2017, which came into effect on April 1, 2017, replacing the previous regulations from 2011. The revised preferential procurement regulations will help optimize procurement strategies in South Africa, although corruption remains a critical issue hindering effective procurement. Multinational medical device companies will
aim to develop strategies that are in line with the country's socio-economic polices to counter the increasing preference for local suppliers. **The revised preferential procurement regulations will make it harder for foreign companies to win government tenders, making local companies more competitive.** Tenders are now geared further to supporting the government's broader objectives: favoring small, medium and micro enterprises (SMMEs), which complement the government's aims of employment creation and income generation using local suppliers.

Among Main Sources

-Extracts from "South African Dental Technicians Council", https://sadtc.org.za/education/
For full Annual Report 2017/2018, https://portal.sadtc.org.za/pluginfile.php/5412/mod_resource/content/0/Annual-Report-for-2017-2018-FY_Final.pdf
-Extracts from "Market Insights: South Africa Medical Devices Market" for Africa Health Exhibition & Congress, by Informa, a leading international events, intelligence and scholarly research group. For full report: AFH19_Industry_Insights_Medical_Devices_Market_REPORT.pdf
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The HPCSA is a statutory body committed to promoting the health of the population, determining standards of professional education and training, and setting and maintaining excellent standards of ethical and professional practice, ensuring continuing professional development and fostering compliance with healthcare standards. All individuals who practice any of the health care professions incorporated in the scope of the HPCSA are obliged by the Health Professions Act No. 56 of 1974 to register with the Council. Failure to do so constitutes a criminal offence.

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SAMED promotes, represents and safeguards the interests of the South African Medical Device and In-Vitro Diagnostics (IVD) industry, focuses on healthcare matters relevant to its members' interests. The association aims to provide member companies - local and multinational - with a collective, objective and credible platform to engage with stakeholders. SAMED's members include individual medical technology companies, associated members and associations

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