



South Africa Striving for Success

Developments in the pharmaceutical sector

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By

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In association with Chiltern International



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About Chiltern International

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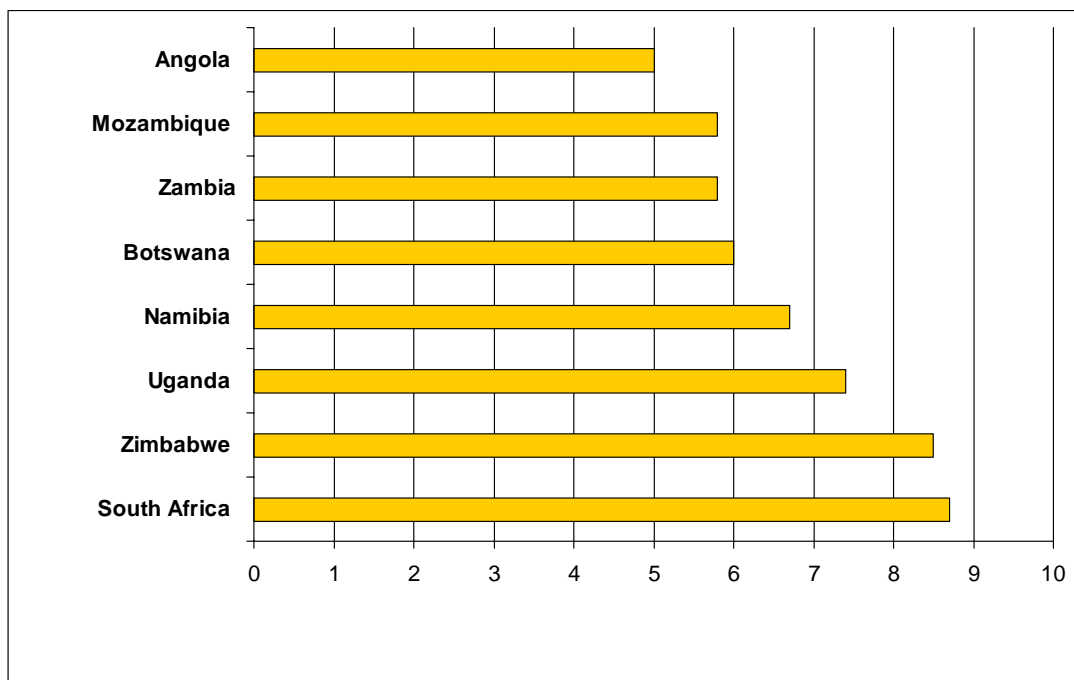
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In the past decade South Africa has become one of the leading markets of interest in the continent of Africa. Many observers believe that it will be the industrial pioneer for the region, as it is in a stronger economic position than many of its neighbours. At present, South Africa has the largest economy in Africa, accounting for over 30% of the continent's GDP and the government is keen to use this as an advantage in developing industries that will allow it to compete internationally¹.

Healthcare ambiguity

Improving public healthcare access is a major priority for the South African government and it is under considerable pressure to deliver on its promises in this area. Despite some advances in expanding access, there remains a large proportion of the population that lack basic healthcare services. The public healthcare challenges are illustrated by figures from the World Health Organization (WHO) showing that even in the 21st century, life expectancy at birth is still only 47 years for males and 49 years for females.

Figure 1. Total expenditure on health as % of GDP



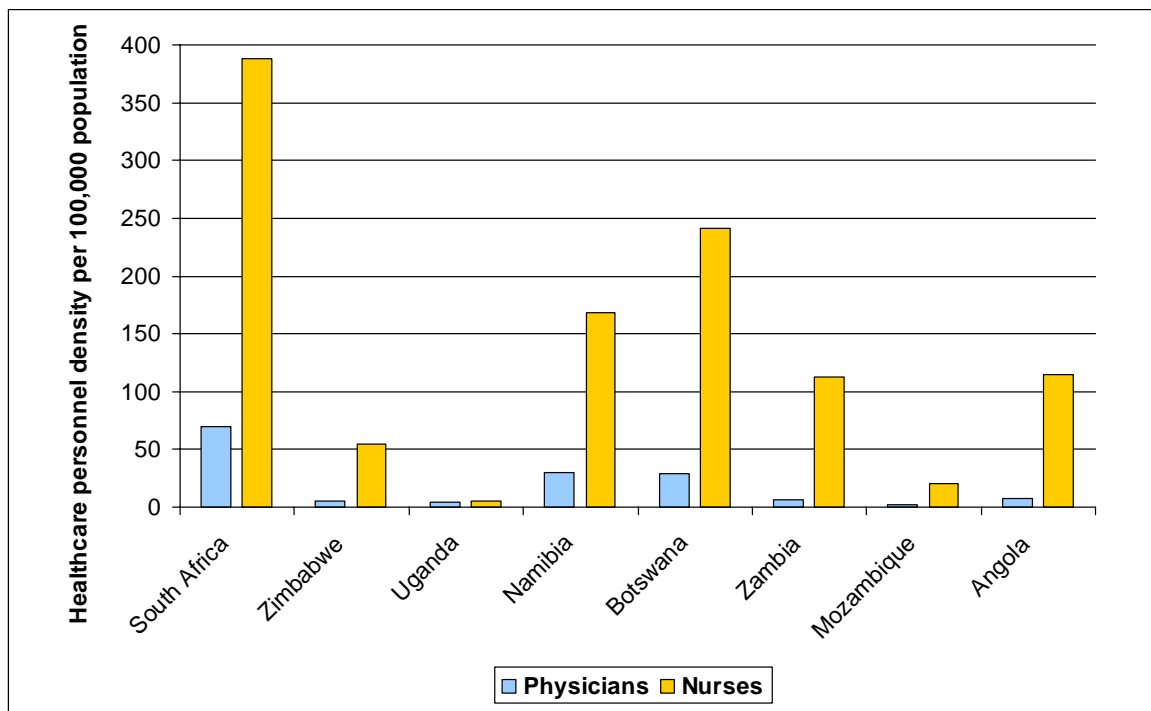
Source: World Health Organization

At present, South African healthcare comprises of a highly sophisticated private system that serves a section of the population who are wealthy enough to afford its services and an over-stretched public system, upon which most of the population relies⁽²⁾. The public healthcare

system is funded at federal (20%) and provincial (80%) levels, but the service offered to the public tends to vary on location⁽²⁾. Despite increasing investment, many public hospitals are characterised by lengthy waiting lists, overcrowding and a shortage of medical supplies. There is also a shortage of appropriately qualified staff and this situation is not helped by healthcare personnel continuing to seek careers abroad rather than stay in the country. For example, in 2003, the UK approved 5,880 work permits for health and medical personnel from South Africa⁽³⁾.

Yet concentrating on the state of the public healthcare system does not give a complete picture of South Africa. The fact is that South Africa has well-established and admired medical research credentials deriving from its private system and the work of its expatriate researchers. For example, it was the location for the first human heart transplant in 1967 and the computed axial tomography scan, or CAT scan, was co-developed by the South African physicist Allan Cormack^(4,5). More recently, the University of Cape Town (UCT) became South Africa's candidate to host the International Centre for Genetic Engineering and Biotechnology (6). This R22 million laboratory is only the third of its kind in the world⁽⁶⁾. The main healthcare focus of the Institute will be biotech initiatives aimed at HIV/AIDS, tuberculosis and malaria⁽⁶⁾.

Figure 3. Human Resources for Health



Source: World Health Organization

Therefore the problem for South Africa is how to use the foundations of its more promising institutions to boost the services and deliverables across its public sector. At the very least, the

technological progress achieved by the richer subsection of society has led to confidence within South Africa that the country can overcome some of the hurdles that continue to hamper modernisation in other emerging economies.

International attention

The existence of a sophisticated medical system, even if it continues to only serve a section of the population, staffed by well-trained medical personnel is attracting international attention. The standard of healthcare at the best institutions in South Africa is considered to be equivalent to that in most industrialised nations and this is evidenced by the country having become one of the major world regions for medical tourism⁽⁷⁾. According to South Africa's Annual Tourism Report, over 100,000 people traveled to the country in 2003 for medical procedures⁽⁷⁾. Certainly the country's existing healthcare infrastructure and continuing investment in improvements offers advantages over other countries in Africa. For example, it is a little known fact that the Baragwanath Hospital located in Soweto is the largest hospital on the African continent^(8,9). The hospital is equipped with 3,250 beds and over 2,000 patients visit its clinics every day⁽⁸⁻¹⁰⁾. Interestingly, many medical students from North America, Europe and Australia seek elective clerkships at the hospital⁽⁸⁾.

Many international pharmaceutical companies are keen to invest in South Africa and see the country as particularly attractive for running clinical trials. There has been a visible rise in clinical trial activity in South Africa, due to the influx of pharmaceutical companies and CROs seeking to capitalise on the availability of investigators with experience of working to ICH-GCP clinical trial standards. Most major companies are actively using South Africa for clinical research and the country seems particularly favored for Phase III work. Major therapeutic areas include infectious disease, oncology and cardiovascular (Figure 3). Both the US Food & Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMA) have accepted data from work carried out in South Africa⁽⁷⁾.

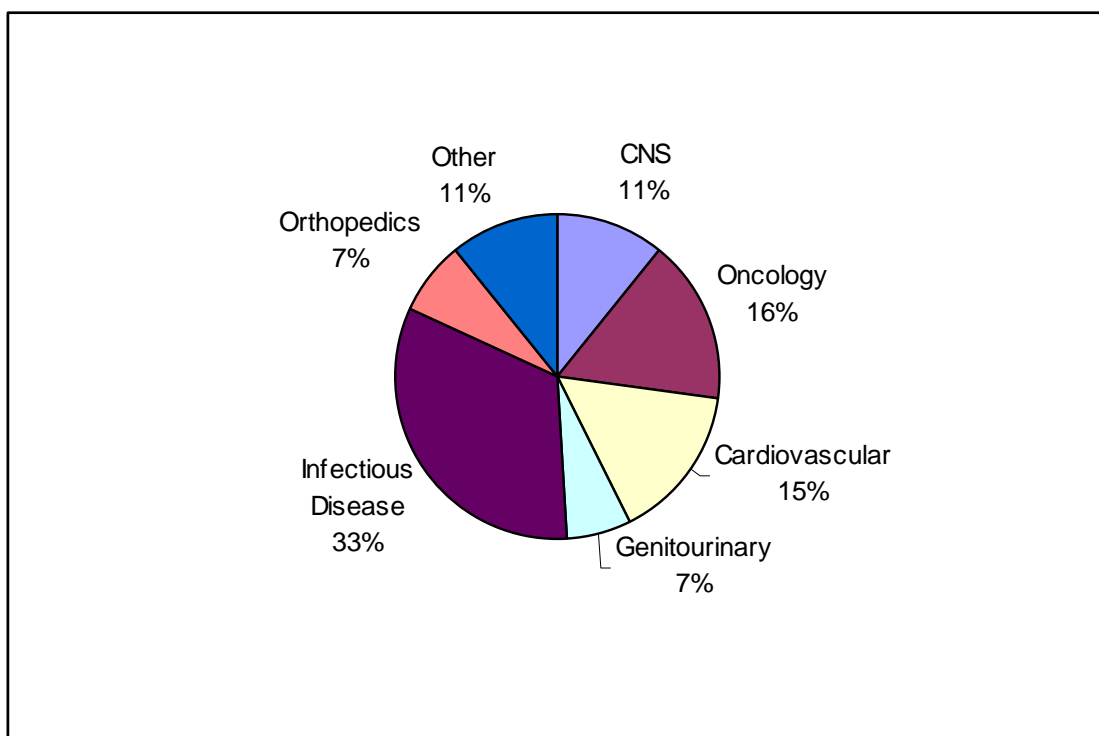
In 1996 a survey was carried out amongst members of the Pharmaceutical Manufacturers Association (PMA) and based on these responses the value of industry-sponsored clinical research was estimated at R425 million⁽¹¹⁾. A similar follow up survey in 2000 by the Wits Health Consortium, extrapolated that the value of industry-sponsored clinical research had grown to R826 million⁽¹¹⁾. The latter survey included both pharmaceutical companies and CROs active in South Africa and also indicated that they had assigned R484 million for capital investment over the next two years⁽¹¹⁾. In 1997 it was estimated that around 55 foreign companies and 92 domestic companies were active in clinical research⁽¹²⁾.

Despite the investment by foreign companies, there are worries in South Africa concerning the intentions of the pharmaceutical industry and this has led to some negative media coverage. As with many other emerging nations, there is public concern that poorer sections of society could

be exploited. This is a particularly sensitive area, given South Africa's troubled history, and so all companies must pay close attention to how their work is perceived.

In response, pharmaceutical companies argue that clinical trials bring valuable revenue into the South African healthcare system, helps physicians develop their research skills and offers patients novel treatment options⁽¹³⁾. The government has stated that clinical research should not be conducted in South Africa, simply because it has the capability to run such studies. It has called on international sponsors to ensure that research conducted in South Africa is relevant to the health needs of the country⁽¹⁴⁾.

Figure 3. Active clinical trials per therapeutic area in South Africa



Source: Chiltern International

Stimulating Domestic R&D

Like many other countries around the world South Africa is keen to develop its pharmaceutical R&D capabilities. The government is particularly interested in developing a world-class biotech sector as this could have economic benefits and also play a useful role in tackling diseases that predominantly affect South Africa.

During the Apartheid regime, South Africa was isolated from the international community and was thus excluded from many developments in the technology field. As a result there was a considerable effort to develop scientific expertise independently within the country to avoid

reliance on external parties. The major areas that benefited from this approach were the arms, mining and textile industries, but as noted earlier, medical research in certain field was fairly advanced. The country now hopes to direct its existing R&D capabilities towards the biotech sector.

Although South Africa has an established reputation in the technological processes involved in brewing and agriculture, it has less experience in applying biotechnology to healthcare. For biotech companies to succeed they will need to apply the latest advances in genetics and genomics to their R&D. In 2001, recognizing the challenges it faced in developing a mature biotech industry, the South African government published its National Biotech Strategy and allocated R400 million over a three year period towards its implementation⁽¹⁵⁾. The country is also taking account of developments elsewhere in the world in order to create a realistic and long-term plan for its future industry.

A recognised weakness of past attempts to stimulate a domestic biotech sector was the lack of coordination between bodies involved in biotech-related research. Therefore a key part of the new national strategy has been to create a number of biotechnology regional innovation centres (BRICs) in order to implement the National Biotech Strategy on both a regional and national scale by acting as focal points for the development of biotechnology platforms. The three BRICS that have been established are BioPAD (Biotechnology Partnerships and Development), Cape Biotech and LIFElab East Coast Biotechnology Consortium (Table 1).

Table 1. South Africa's Biotechnology Regional Innovation Centres (BRICs)

BRIC	Location	Goals
BioPAD (Biotechnology Partnerships and Development)	The Innovation Hub Science Park, Pretoria	The application of biotechnology to industrial growth through process and product development, mining competitiveness and environmental rehabilitation or prevention of adverse environmental effects
Cape Biotech	Black River Business Park, Cape Town	Industry stimulation and capacity creation, and disseminating and managing government funds by investment in promising projects in human health.
LIFElab - East Coast Biotechnology Consortium	East coast region (including Durban, Pietermaritzburg, Nelspruit and Grahamstown).	The two primary programme areas are human health and bioprocessing.

The primary role of the BRICs is to implement the strategy by investing the allocated R400 million funding in start-up biotech companies and developing human capacity to support the

growing industry through various capacity development programmes. The BRIC activities will be overseen by the Biotechnology Advisory Committee (BAC), which will ensure development of the sector on a national level through the coordination and integration of the regional activities. Furthermore, by training local scientists in the field of biotechnology, South Africa will have a resource base to staff the industry as it develops in the future⁽¹⁾.

A continuing problem for the biotech sector in South Africa is the poor availability of funding. Although the government is providing investment, this will be insufficient on its own to stimulate a mature biotech sector. In 2001, the government identified around 68 venture capital firms in the country, which controlled R28 billion, but few were found to be enthusiastic about funding the emerging biotech sector⁽¹⁵⁾. This can be attributed to a lack of understanding of both the industry and risks involved. In order to encourage greater involvement, a national conference, Bio2Biz 2004, was launched to address commercialisation issues unique to this industry and to provide private investors the opportunity learn about the industry and to meet with potential projects⁽¹⁾.

Healthcare controversy

Aside from increasing investment in healthcare, the government would like to stimulate relevant domestic industries so that they can contribute to reducing the healthcare disparities that continue to exist. At present, the R&D efforts of major international companies are not seen publicly as placing a high enough priority on the diseases that predominantly affect Africa. Critics also believe that the stance taken by pharmaceutical companies over intellectual property has skewed research priorities and stands in the way of widening healthcare access in developing world regions. This situation was highlighted in the dispute between the South African government and a number of multinational pharmaceutical companies concerning AIDS treatments, during the late 1990s.

On a global basis, the laws relating to pharmaceutical patents are in principle regulated by the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁽¹⁶⁾. The philosophy behind the TRIPS agreement was to ensure that the manner in which intellectual property is protected also serves social goals.

The TRIPS agreement has been put to the test by the ongoing global HIV crisis, which has had a devastating effect on South Africa. The most rapid increase in South Africa's HIV prevalence took place between 1993 and 2000, during which time the country was distracted by major political changes⁽¹⁷⁾. In 2004, an estimated 6.29 million people were living with HIV and South Africa continues to struggle in dealing with the healthcare crisis caused by the disease. The situation has not been helped by various senior South African politicians downplaying the role of HIV in causing AIDS^(18,19). The political stance contrasts dramatically with that in Brazil, where the government implemented a bold strategy to deal with the crisis and made AIDS treatments

available free of charge to all citizens who needed them through the country's public health care system^(20,21). The Brazilian approach has been widely commended for reducing the impact of HIV in the country^(20, 21).

Table 2. Philosophy of the TRIPS agreement

Article	Key points
Article 7: Objectives	Intellectual property protection should contribute to the promotion of technological innovation to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare.
Article 8: Principles	Appropriate measures may be needed to prevent the abuse of intellectual property rights by right holders.
Article 27 : Patentable Subject Matter	Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application
Article 29 : Conditions on Patent Applicants	An applicant for a patent shall disclose the invention in a manner sufficiently clear for the invention to be carried out by a skilled person.
Article 30: Exceptions to Rights Conferred	Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the patent holder's legitimate rights.

Whilst those with AIDS in wealthy nations have been able to gain access to new treatments, they remain beyond the reach of the majority of sufferers in South Africa. As a result, progress on the scientific front to develop effective treatments for AIDS has been overshadowed by their costs^(1,16). The South African public and media have been vocal in their criticism of the pharmaceutical industry's pricing of anti-retroviral drugs. In their defence, pharmaceutical companies state that the healthcare situation in developing countries is complex, and that issues such as the general healthcare infrastructure, establishment of efficient drug distribution systems and training for healthcare personnel must be tackled alongside the development of new treatments.

In 1997, the South African government decided to set aside international guidelines on intellectual property, stating that the enormity of the AIDS crisis gave it "medical emergency status". Under TRIPS Article 31, countries may use compulsory licensing for domestic pharmaceutical supplies during health emergencies⁽¹⁶⁾. This led to a legal battle with the pharmaceutical industry, which led to considerable adverse publicity for the companies involved. Following a statement by the government that its legislation would be implemented in a TRIPS-compliant fashion, the action by the pharmaceutical companies was withdrawn⁽¹⁶⁾. Despite this, the relationship between the South African government and the pharmaceutical industry has remained uneasy.

Regional pioneer

One of the specified aims in the South African National Biotech Strategy is to direct some of the domestic biotech R&D effort towards areas of unmet medical need. This would allow it to become less dependent on outside research efforts. All BRICS are being encouraged to invest in relevant projects, and it is hoped that they will eventually attract foreign interest in their work. For example, there has been foreign interest in the bioinformatics approaches being used by South African research groups for areas such as AIDS, dengue fever, tuberculosis and other tropical diseases⁽²²⁾. The South African AIDS Vaccine Initiative (SAAVI) which was established in 1999 to coordinate the research, development and testing of HIV/AIDS vaccines in South Africa. SAAVI works with a range of national and international partners, but focuses primarily on the development of subtype C HIV/AIDS vaccines (as HIV subtype C accounts for over 90% of infections in the southern African region)⁽²³⁾. SAAVI's expertise will be important for testing vaccines developed by the companies funded by the BRICs.

South Africa's efforts to develop its biotech sector can serve as a useful example for developing countries around the world. Africa could benefit enormously from biotech advances, both from an economic standpoint and in terms of health improvements for the local populations. In July 2005, the African Union announced that it was setting up a biotechnology advisory panel⁽²⁴⁾. In the biomedical field, the panel hopes to draw upon the expertise of South Africa's emerging biotech sector⁽²⁴⁾.

The country is also keen to make an international impression and so in October 2005 it hosted a bio and medical technologies conference called Lifesparks 2005. The event was primarily funded by the Innovation Fund, a government initiative, to promote the biotech sector and enable prospective entrepreneurs to meet with potential business partners⁽²⁵⁾. The Innovation Fund also showcased thirty of its biotechnology projects⁽²⁵⁾. Events such as these will be important to demonstrate to an international audience that the emerging South African biotech sector is innovative and represents a potential source of new medicines.

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