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2015 life sciences outlook South Africa

South Africa's pharmaceutical market, the largest in Sub-Saharan Africa, is fairly well-developed and totaled an estimated $3.9 billion in 2013. Revenue growth has been constrained in recent years by government price regulations, slowing economic growth and and the subsequent weakened purchasing power of most of the population. Although these trends will continue in 2014-2018, the market is anticipated to grow by an average of six percent a year, to an estimated $5.1 billion.[1]

South Africa currently has the most developed manufacturing base in Africa, with a considerable number of life sciences companies headquartered in the country. These include global generics manufacture such as Aspen and Adcock Ingram, as well as globally renowned biotechnology companies such as Genius Biotherapeutics.

South Africa's pharmaceutical market = $3.9 billion in 2013

Growth rate = 6 percent annually in 2014-2018

South Africa has a two-tier pharmaceutical market. The public sector tier is characterized by high demand and low prices caused by low levels of funding. The private sector tier has drug prices similar to those in the developed world. The government sets a single exit price (at ex-factory level) for all prescription medicines, regardless of the channel through which they are purchased.[2] Recently, the annual increases on the single exit price have not been in line with the recommended/published equation to calculate this increase. This has had a negative impact on the sector, which is still heavily reliant on imports – and as such has been negatively affected by the devaluation of the ZAR against the U.S. dollar and Euro.

The government's national health plans are expected to boost demand for lower cost drugs—especially generics—in coming years, as is its commitment to provide greater access to anti-retroviral (ARV) medication within the public health system to combat the HIV/AIDS pandemic.[3] Generics currently account for around 60 percent of the overall market in terms of volume, but because of their low cost, around one-third in terms of value. The government procures mass volumes of generic products via tender. However, the private market for generic drugs is growing; the higher prices paid by the private sector help to subsidize the low-cost generics made available to the public sector.[4]

1 *Industry Report, Healthcare: South Africa,* The Economist Intelligence Unit, June 2014
2 Ibid
3 Ibid
4 Ibid

Currently, innovative pharmaceutical products are not well represented on South Africa's essential drug list, which includes products that are available through the public healthcare system. The opportunity for such products to enter the market exists, as does the opportunity to introduce more innovative pricing models, such as a value-based pricing in which reimbursement is based on a drug's clinical effectiveness.

A significant number of international life sciences manufacturers have a presence in South Africa through direct manufacturing facilities, distribution operations, or licensing agreements.[5] To grow the relatively small scale of local pharmaceutical manufacturing, the government is initiating a number of industrialization policies and programs. Among these are the ambitious Ketlaphela project, which intends to manufacture active pharmaceutical ingredients in South Africa by 2017 and is currently seeking international technology and investment partners.[6] The manufacture of APIs in South Africa via Ketlaphela could potentially add another competitor to the market and increase South Africa's ability to supply increasing domestic and global supply.

The South African medical environment is the most regulated on the African continent. There is pending discussion on further regulating the sector, which some argue will stifle competition and increase prices, while others justify additional regulation as necessary to limit price inflation. Among recent initiatives, the government has drafted new IP regulations in recognition that South Africa lacks a unified, well-coordinated IP policy. The government is also implementing legislation to speed up the drug registration process, make South Africa more attractive as a destination for clinical trials, and increase the overall competitiveness of the country's life sciences market as a whole. Currently, the Medicines Control Council (MCC)[7] is South Africa's primary regulatory agency for the manufacture, distribution, and marketing of medicines in the country. One of the key challenges it faces is long delays in the regulatory approval process. (MCC employees are qualified professionals who work on a part-time basis, sometimes resulting in significant delays when it comes to approval of medicines.) To address this and other regulatory issues, MCC is set to be replaced by the South African Health Products Regulatory Agency (SAHPRA),[8] which will be tasked with regulatory responsibility across the life sciences sector—pharmaceuticals, biologics, medical devices and in-vitro diagnostics, complementary medicinal products, foods, and cosmetics. It is, however, not exactly clear when the transition to SAHPRA will be completed.

South Africa has a well-developed scientific base in terms of existing infrastructure and human capital. Leveraging both of these factors, coupled with the appropriate strategic focus, could potentially unlock significant value on a fast-growing continent. Local companies should seek to forge partnerships with international partners to secure their investment and transfer of knowledge and technical expertise. This applies all across the life sciences value chain.

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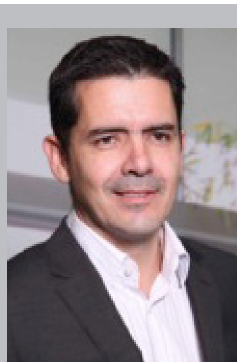
5 *Industry Report, Healthcare: South Africa,* The Economist Intelligence Unit, June 2014
6 Ketlaphela; South Africa's government's ARV manufacturing project enters next phase; http://www.gov.za/speeches/view.php?sid=36609, 2013
7 *Medicines Control Council:* http://www.mccza.com/about/default.asp
8 *17 Government Gazette No 37579 of 22 April 2014 – Notice R 315 "Medicines and Related Substances Act (101/1965).*



Valter Adão
LSHC Industry Leader
Deloitte Southern Africa
+27 11806 6117
vadao@deloitte.co.za

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