# SOUTHARICA: Health Disparity versus PHARMAOPPORTUNITY

With a population of 50 million, South Africa is a multilingual, multiracial, and politically stable nation.

outh Africa has been ranked by the World Bank as an upper-middle income country and is the largest economy in Africa. Yet, South Africa has a huge divide be-

tween the haves and have nots. Around 8 million people, 16% of the population, are covered by health insurance, with the vast majority using the public health system. According to Espicom, the deep division between public and private healthcare leaves the majority of the population without medical care.

"For patients in outlying areas, and areas outside the major cities, healthcare of any sort can be a challenge," says Zane Wilson, founder of the South African Depression and Anxiety Group (SADAG). "For many rural and outlying areas, clinics and hospitals are many miles away and even if there are clinics in the area, many are under-resourced."

#### **Government Initiatives**

Financial investment in life-science R&D by the South African government is mostly limited to funding for specific projects for HIV/AIDS, malaria, and TB, or one-off investments of up to US\$10 million to research institutes, says Patrick Flochel, partner, global pharmaceutical sector leader, EY.

"At the same time, the government has shown a strong commitment to develop a future investment and promotion strategy for life-sciences in the country," he says. "The government's Ten-Year Innovation Plan (2008–2018) aims to place South Africa among the top three emerging economies in the pharmaceutical industry, by leveraging the nation's biodiversity and indigenous knowledge and innovation. As part of this plan, the government also aims to build five R&D centers of competence focusing on national health priorities, which are expected to work in close collaboration with the local industry. And there is a plan to attract foreign investment in pharma R&D."

Mr. Flochel says the government also has entered into a private partnership to build out capacity for healthcare services.

According to industry reports, the South African government has established the Joint Public Health Enhancement Fund, attracting investments of R40 million (US\$4.5 million) from 23 companies to support efforts to improve the public health system over the next three years.

Referring to a report from Health-e, Mr. Flochel says the fund will be used to boost the number of medical students and improve their training, as well as fund research in the areas of TB and HIV.

Other government initiatives to promote R&D include: setting up the International Centre for Genetic Engineering and Biotechnology for conducting research on such diseases as the African sleeping sickness, bilharzia, malaria, and HIV/AIDS.

Collaborations between academia and MNCs are also expected to benefit patients.

In February 2013, the University of Cape Town and the Novartis Institutes for BioMedical Research (NIBR), announced a research initiative to advance medicines to treat African patients. The collaboration with the university's Drug Discovery and Development Centre (H3-D) aims to build drug discovery and development capabilities in Africa, and to develop an FDA-level clinical study site in Cape Town to conduct proof-of-concept studies of

#### South Africa at a Glance

Total Population:	50,133,000
Gross national income	
per capita (PPP international \$):	10,360
Life expectancy at birth m/f (years)	: 54/55
Probability of dying under	
the age of 5 (per 1,000 live births):	47
Probability of dying between	
the ages of 15 and 60 years	
male/female (per 1,000 population	<b>):</b> 521/479
Total expenditure on health	
per capita (Intl \$, 2010):	935
Total expenditure on health	
as % of GDP (2010):	8.9%

Note: Figures are for 2009 unless indicated. Source: Global Health Observatory



new compounds developed at H3-D. Additionally, Novartis provides H3-D with new chemical starting points for the design of medicines against TB, and the companies conduct joint programs on malaria research with the Singapore-based Novartis Institute for Tropical Diseases (NITD).

In an effort to boost local manufacturing given the country's dependence of imported active pharmaceutical ingredient (API), the government has taken several steps, such as providing tax incentives and implementing preferential procurement policies for locally manufactured drugs. It has also co-invested with multinational corporations (MNCs) to encourage them to start local production.

For example, the South African government has partnered with Lonza to set up a US\$210 million plant to produce antiretroviral APIs. The plant is expected to become operational in 2016. The government also has set up a human vaccine manufacturing facility, the Biovac Institute, under a public—private partnership between the government, Litha Healthcare Holdings (South Africa), Heber Biotech (Cuba), Bionet (Thailand), and Disability Employment Concerns Trust (South Africa).

#### Pharma Presence

The South African pharmaceutical market is valued at US\$4.1 billion (ZAR30.3 billion, according to IMS March 2012 MAT). The industry can be broadly classified into two sectors: the private sector, where products are

sold to pharmacies, dispensing doctors, hospitals or, in case of OTC medicines, to retail outlets; and the public sector, where products, such as antiretro virals are distributed to state hospitals and clinics.

Both domestic and multinational pharmaceutical companies are present in South Africa's pharmaceutical market, Mr. Flochel says. (See chart on the following page for the top 20 pharmaceutical companies.)

"In fact, the country is fast becoming a base for MNCs looking to penetrate into the Sub-Saharan Africa region," he says, noting that four of the five leading companies by market share are MNCs (Sanofi, Cipla Medpro, AstraZeneca, and MSD), while Aspen, which is ranked No. 1 in the market, is the only domestic company among the top five.

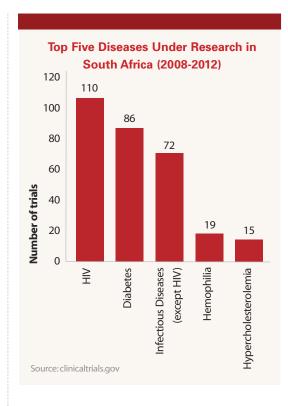
Mr. Flochel says most MNCs have a direct presence in the country through subsidiaries. Some companies, such as Sanofi, Pfizer, GSK,

Roche, and Novartis, have their own manufacturing facilities in South Africa. Others, such as AstraZeneca, Merck, and Abbott, primarily use South Africa as their distribution and management center, without directly investing in manufacturing. Some Indian companies, such as Aurobindo Pharmaceuticals, Alkem Laboratories, and Ranbaxy Laboratories mainly operate in the country through liaison offices to import their products.

"MNCs have mainly focused on selling innovative drugs to the private sector in urban areas as well as targeting vaccines, anti-infectives, and diabetes," he says. "They have not made many inroads in the public sector, which tends to favor domestic players."

In terms of value, the private sector accounts for almost 85% of the overall pharmaceutical market, according to March 2012 research from Adcock Ingram. According to EY calculations, original drugs — both patented and off-patented original branded drugs dominate the private pharmaceutical market, contributing almost 46% to the total, owing to their high prices as a result of a lack of competition and constant demand. Generic and OTC drugs contribute 26% and 28% to the private market, respectively. The public sector market is mainly tender-driven and predominantly comprises generic products. In terms of volume, the private sector accounts for 60% of the overall pharmaceutical market, and the private sector accounts for the remaining 40%.

In terms of volume, OTC medicines dominate the private sector or about 73%, while original drugs account for a mere 9% by vol-



ume. But experts say, increasing demand for generic products is forcing the private prescription market to change.

According to the same March 2012 report from Adcock Ingram, generics grew by 13% by value and 6% by volume compared with branded drugs, which grew by 4.6% by value and 3.2% by volume.

Domestic pharmaceutical manufacturing in South Africa is at a nascent stage. Imports constitute almost 55% of the total South African pharmaceutical market, by value, and India is the country's most prominent trading partner, according to a Business Monitor International report.

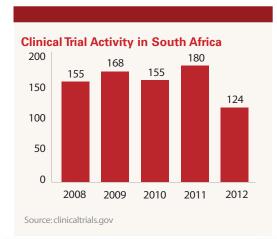
#### In the Clinic and on the Market

Of the 124 clinical trials conducted in South Africa in 2012, 64 were in the midstage of drug development — Phase II and Phase III.

Mr. Flochel says most multinational companies conduct early-stage trials in their home markets, and move to South Africa due to the availability of a large pool of treatment-naïve patients.

HIV dominates the clinical research activity in the country, followed by diabetes and infectious diseases other than HIV.

"With the increasing prevalence of lifestylerelated conditions, research on conditions such as diabetes and hypercholesterolemia has also been gaining momentum," Mr. Flochel says. "Although it is hard to attribute better health outcomes to clinical research alone, continuous





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**ZANE WILSON** 

The South African Depression and Anxiety Group

R&D efforts in the pharmaceutical industry and better access to innovative medicines have led to decreased mortality rates, decreased rates of hospitalization, and improvement of overall health in the country.

According to a December 2012 report from Economist Intelligence, the number of deaths from AIDS declined from 370,000 in 2005 to 270,000 in 2011.

Mr. Flochel notes that South Africa is not always viewed as a favorable location for clinical trials, because of excessive red tape and the under-funded, under-staffed Medicines Control Council (MCC), which is slow to approve projects.

The drug approval process in South Africa is complicated, mainly due to regulatory delays, Mr. Flochel comments. MCC, which is responsible for the approval and the ongoing scrutiny

of pharmaceutical products in the country, takes four to six months to review applications, much longer than in other regions. As a result, the average approval time for generics in the country is 24 months and for ethical products the approval time is 36 months.

"The new drug regulatory body, the South African Health Products Regulatory Authority (SAHPRA), is expected to replace the MCC," he says. "The SAHPRA will be more powerful and an independent body, with its CEO reporting directly to the Ministry of Health."

An article in NSP Review from October 2012 notes the SAHPRA is expected to model its structure on the lines of the U.S. FDA, and is likely to derive a large part of its funding through user fees from applicants.

#### **Patient Challenges**

South Africa has a very high rate of HIV infection and along with that, TB is prevalent.

"There is a big concern that people are not treatment compliant, which leads to treatment-resistant strains of infection," Ms. Wilson says. "There is still a lot of stigma surrounding both illnesses and people are still hesitant to seek treatment; despite many education programs, people remain ignorant of how the illnesses are contracted and treated."

There is still a culture in which patients seldom question their treatment and listen to what doctors or nurses say, as a result many patients don't understand what they are being treated for or what the treatment will do for them.

"As a result, compliance to treatment regimens is often bad and patients frequently stop taking their medications," she says.

Ms. Wilson adds that while there are NGO and some government initiatives to educate the public about cancer, diabetes, malaria, mental health, and heart disease, many of these initiatives never reach disadvantaged regions.

"In addition, most healthcare education projects rely on volunteers or trainers, and there is often a severe lack of manpower for this to be sustainable," she says.

Health literacy is a particular problem, she notes.

"Rural communities often lack even basic education, which results in even poorer health literacy," Ms. Wilson says.

She notes that mental health issues such as PTSD, depression, and substance abuse are prevalent in South Africa, yet mental illness is still largely ignored and, outside of the main cities, there are very limited resources — if any. The problem is that there are too few clinics, and they are under-staffed or under-resourced.

### Top 20 Pharmaceutical Companies in South Africa

		MAT June 2012
Rank	Company	Market Share (%)
1	Aspen Pharmacare Gen	7.8
2	Sanofi	7.2
3	Cipla Medpro	5.1
4	AstraZeneca	4.5
5	MSD (Pty) Ltd.	4.3
6	Pfizer Labs	3.8
7	ADCO-Generics	3.6
8	Aspen GSK	3.3
9	Roche Ethicals	3.0
10	Adcock OTC	3.0
11	Janssen	2.8
12	Novartis	2.7
13	Bayer Schering Pharma	2.7
14	Abbott	2.0
15	Sandoz SA (Pty) Ltd	2.0
16	Aspen Pharmacare OTC	2.0
17	Novo Nordisk	1.8
18	Lilly	1.6
19	Boehringer Ingelheim	1.6
20	Johnson & Johnson	1.5

Source: Cipla Medpro, interim results, 2012

An emerging trend is that of training lay counsellors, community healthcare workers, and home-based caregivers on patient education, the importance of treatment compliance, and the safe use of medicines, as well as basic counselling skills.

"Home-based caregivers and community workers are being mobilized to provide onthe-ground help and support for residents to increase the level of care and contact with patients, increase treatment compliance, and help patients who may be too sick or too poor, to access clinics regularly," she says.

Another initiative, created by SADAG are battery-powered Speaking Books that seek to provide patients with health education, awareness, and empowerment, Ms. Wilson says.

"At the press of a button, the text of the books are read out loud so that patients with low levels of literacy or who are too sick, old, or young to read can still have access to life-saving information," she says. "The books help empower communities and individuals to take responsibility for their health and well-being."







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## South African MENTAL Healthcare in Decline

Depression is predicted to be the second-leading disabling health condition in the world by 2020, yet mental health therapy is often inaccessible or unavailable.

ccording to Zane Wilson, founder of the South African Depression and Anxiety Group, with the recent global recession, poor households have

sunk deeper into poverty and many more South Africans are finding themselves steeped in financial woes.

One in five South Africans may suffer from a mental disorder, but only 15.9% of them receive treatment.

According to many experts, South Africa has some of the best mental healthcare legislation in the world. But mental health is the Cinderella condition of the public healthcare system; it is sidestepped and certainly not a priority of the department of health. Psychiatric patients all too often are talked about in whispers in dark corridors or they are left alone and scared, with their questions unanswered in emergency rooms and general wards.

Ms. Wilson says the Mental Health Care Act (2002) is a piece of ground-breaking legislation that is unfortunately not covering much ground in the real world.

Some 84% of the country's estimated 55 million depend on government hospitals and clinics, which are greatly overburdened. Only 17.6% of people have health insurance, which reached almost 71% of whites, but just 10.3% of the black population, according to National Statistics Agency.

"Patients are falling through the cracks in a

healthcare system that is underfunded and under-resourced," she says. "Attempted suicide patients are regularly not admitted. Instead, they are sent home after a stomach pump without therapy, a follow-up appointment, safe medication, or care. It is with this in mind that the South African Depression and Anxiety Group has been instrumental in developing more than 200 support groups countrywide in some of the most remote areas to assist patients with their right to care and treatment.

"It is common for patients to be sent to hospital pharmacies only to be told the prescribed medication is not in stock," she says. "They either have to change medication or wait until the right pills are available. This is not the way to treat people who scrape together money to get to the hospital, only to spend a whole day being shuffled from department to department."

Ms. Wilson says South African society tends to regard depression as a "female" illness and the lack of treatment across the health sector is a national problem.

"Five times as many men commit suicide as women," she says. "This means that 82% of the suicides in South Africa are committed by men, yet the subject of male depression is still largely taboo and not a topic that men are likely to chat about casually at a braai, or share with their colleagues."

The current trends of retrenchment, unem-

ployment, and restricted medical benefits mean access to private healthcare treatment is no longer an option for an increasing number of South Africans.

"The obvious stresses that accompany unemployment — daily worries about paying bills, putting food on the table, relationship failures, and a drop in social status — results in a downward spiral into depression, which affects even the strongest.

"To compound the issue, dealing with health problems is much harder for those with less money," Ms. Wilson says. "There are fewer treatment options, longer times spent in waiting rooms, as well as the stigma of visiting a clinic or government hospital for help. For people who suddenly find themselves without jobs, family, money, or medical aid the harsh realities of life can be too hard to bear."

South African studies have linked family problems and interpersonal conflicts with suicidal behavior and conditions, such as mood disorders and substance abuse. Men often show their stress by working too hard, drinking, or having extramarital affairs. They display aggression rather than depression.

"Mental health diagnosis and recovery can be challenging," she says. "Ensuring that patients maintain treatment regimens so they can recover and stay well is often a long process and one that needs support, supervision, and access to professional care. Yet, de-



ture leaders," she adds. "With 21.4% of youths in South Africa attempting suicide, this is nongovernmental organizations (NGOs) can be an integral part of the government's efforts."

One of SADAG's initiatives is the distribution of battery-powered Speaking Books that help provide patients with health education, awareness, and empowerment.

Although more South Africans suffer from a mental illness than any other chronic disease, fear, discrimination, misinformation, inadequate treatment services, unequal access to

mental health rights of patients are severely compromised.

"NGOs are mostly carrying the load for the mental and emotional wellness of South Africans," Ms. Wilson says. "However, without sufficient funding or support, this cannot continue for much longer. Mental illness costs individuals, companies, and communities billions of dollars every year because of absenteeism and loss of employment, medical bills, worsening of chronic illnesses and hospital visits, abuse, and imprisonment. South Africa can

Created by SADAG, batterypowered Speaking Books seek to provide patients with health education, awareness, and e2mpowerment.

no longer afford to be insensitive about mental healthcare nor can government afford to keep mental illness of lesser importance than major illnesses such as HIV and AIDS, TB, or diabetes."