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South Africa: Searching for a New Model

Under hefty pressure in its fight against the HIV/AIDS epidemics, which ravages the country with an estimated 28% infection rate of the total population, the SA government has fought its way to get multinational companies to lower their ARV treatment prices, or grant 'voluntary licenses' to other companies allowing them to produce their drugs at cheaper prices. The case has attracted media coverage around the world, and was seen by many as a test. The SA government won the legal battle.

The government fight over drug prices is not limited to ARV treatments. For the past three years the government policy has been focused on reducing costs. Prices were frozen in 2003 and in 2004 a new and much more transparent pricing regulation: the Single Exit Price (SEP) was introduced. This regulation was challenged in the courts (another legal embroilment illustrating the traditionally frosty government-industry relations) by pharmacists. The matter was arbitrated by the Constitutional Court which ruled in favor of the government ending months of uncertainty.

Multinational companies still control 80% of the market, but the government's favorable position towards generics and falling prices could deter further foreign investment

According to IMS the implementation of the SEP at the manufacturer level resulted in a 21% reduction in ex-factory prices since December 2003. But the impact was different from one company to the other, as in order to evaluate the SEP, the government conducted a thorough survey on a company-by-company and product-by-product basis, to eliminate the discount and bonus system that previously drove the pricing environment.

There could be more price slashing ahead explains Vicki Ehrich, COO of the Pharmaceutical Manufacturers Association of SA (PMA): "We are in the second phase of the three stages of the pricing regulations. The first one was to bring in the SEP the second stage is to do international benchmarking against a selected basket of countries."

The second phase should not be as painful and PMA has already conducted its own benchmarking, "A survey undertaken by the membership showed that, on our weighted volumes of SA, our prices across the board were about 15% lower than in the five countries where we compared them," explained Ehrich.

According to another survey published by local generic manufacturers published in February 2005, selling prices of generics are also acceptable. "In most cases, generic pricing



Credit: Phelophepa art competition

in SA was lower than their counterparts in Brazil, Australia, Canada, Germany, UK, USA and the Netherlands. For this study we compared 42 generic medicines and 38 of those 42 were cheaper in SA," said Muhammad Bodhania, president of the National Association of Pharmaceutical Manufacturers (NAPM).

Despite the 21% price decrease that followed the implementation of the SEP, the market share of generic drugs in value increased by 3.5 points to 23.5% within three years. The generic market in South Africa is booming as it benefits from public awareness campaigns and advantages given by the government such as the implementation in May 2003 of a mandatory generic substitution regulation.

Another of these advantages is the January 2003 amendment to the SA Patents Act. It aimed at legalizing pre-patent expiry "reverse engineering" research in order to enable early entry of locally manufactured generic copies after patent expiry with a minimum delay. The above provisions, often informally referred to as "South African Bolar", allows R&D work to be undertaken for medicine registration. The manufacture of commercial quantities, imports or exports of generic copies before patent expiration are not allowed.

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Generic sales can only improve with the imminent patent expiry of a number of major HIV/AIDS drugs, notably AZT.

Following a government \$578 million tender, local supply capacity for ARV drugs has expanded tremendously. Aspen, the leading generic company should be the first to benefit from this as it already manufactures as much as eight ARVs products under voluntary license and won the lion share of the government's tender in March. Local generic



Vicki Ehrich,
COO, PMA

companies should use the rising domestic demand and rising production standards as a springboard to develop exports. Aspen and Adcock Ingram are currently the two national champions.



Val Beaumont,
executive
director, IMSA

The government's favorable position towards generics and falling prices could deter further foreign investment from multinational companies. The latter still controlled 80% of the pharmaceutical market in 2003, Pfizer leading the way, but their margins have been considerably impacted while sales are stagnating.



**Muhammad
Bodhania,**
president,
NAPM

The only immediate relief for those companies would be to expand the base of patients covered by private healthcare insurance. In SA, there are two very distinct markets: the public and the private sector.

Multinational companies mainly cater for the private market, as their ethical products are often unaffordable for those depending on the public sector. Only those who are able to afford private health insurance have access to the

private sector and only seven million South Africans, out of 45 have access to ethical drugs.

The stakeholders of the pharmaceutical industry are trying to find solutions to shift at least seven million patients from the public to the private system. This would alleviate the public sector and could double the target market for ethical drugs.

The discrepancy existing between the public and the private healthcare sector is a legacy of the apartheid. Aiming to reduce such inequalities inherited from the former regime, the government has launched the very vast Broader Black Economic Empowerment (BBEE) initiative, and draws tailored implementation charters for each economic sector.

The draft of the Healthcare Charter is devoted to describing challenges facing the healthcare sector, from the chasm between the services patients get at a private or a public facility, to the drastic shortage of nurses and doctors (SA is short of 50,000 health-personal due to 'brain drain'). It has also set up very strict goals to achieve:

By 2010: 60% of staff must be black, 50% women, 60% of procurement must be from black owned firms or persons
By 2014: 70% of staff must be black, 60% women, 80% of all procurement must be from black owned firms or persons.

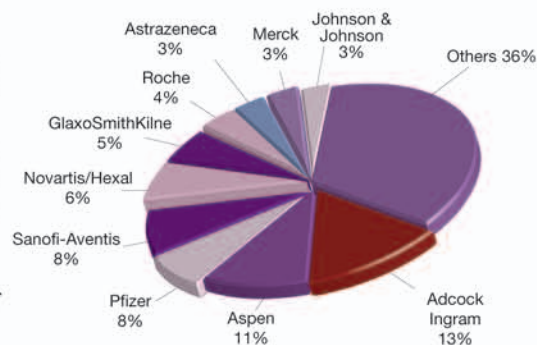
However, the most controversial part of the charter was the issue of ownership: the draft stipulated that all healthcare industry players should immediately be 25% black owned, at least 35% by 2010, and 51% by 2014.

Many in the industry judged this target unrealistic given the structure of international companies. "Most of the aspects are not an issue for us," said Val Beaumont executive director of Innovative Medicines South Africa (IMSA), a new interest group created by Novartis, Roche, Eli Lilly, Pfizer, MSD and Sanofi Aventis, which claims to have a more collaborative than confrontational approach to the government.

Beaumont added: "Considering how big multinationals are created and run globally the biggest challenge is to give-away or transfer part of the ownership of their subsidiaries. Nevertheless as we are committed to contributing to the charter process, we have made proposals to the DOH around possible projects to increase access, equity, and quality in healthcare."

After the publication of this first draft, the key players of the healthcare industry united within the Private Healthcare Forum (PHF) to make counter proposals to the government. "The objective (of the HCC) is to bring quality healthcare to the people of SA within an environment which was created by our history and is still very fresh in our minds, so it is quite complex," said Dr. Fazel Randerer, chairman of the PHF. "The HCC has created an opportunity for things to work out both in the private and in the public sectors, and this opportunity should be grabbed."

Total Private market ending June 2005



Source: IMS

In November 2006 the Minister of Health has agreed to the creation of a steering committee with all the industry stakeholders, and the final text of the charter was to be released in February 2006. Let's hope the fact that none of the stakeholders have so far taken any legal action against this text marks the beginning of a more constructive relationship between the SA government and the industry.

Corrections

In the report on Turkey published in the November edition of Pharmaceutical Executive, page S5. The photo of Mr. Eczacıbasi is mislabeled, he is president of the IEIS not of the AIFD. Also in this article the general secretary of this association is Mr. Turgut Tokgoz.

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Healing The Nation

Over the next 10 years, around six million South Africans are expected to die from AIDS-related illnesses, according to a local government survey. Current estimates put sufferer numbers around five to five and a half million out of a total population of 45 million. According to an Actuarial Society of South Africa (ASSA) report, approximately half a million South Africans infected with the virus are currently in dire need of ARVs. The pandemic is not restricted to HIV/AIDS, but also includes disturbing levels of TB infection and fatalities.

Such a dramatic health situation calls for a plethora of support systems. Several programs have been established in SA to create awareness around these diseases, promote behavior change and provide medical, social and economical assistance to those affected.

Government is also providing support and funding to scientists attempting to develop an HIV immunity vaccine. Trials are being conducted by the SA AIDS Vaccine Initiative as part of the International AIDS Vaccine Initiative. But until that day, the only hope to improve and prolong the lives of victims is through ARV therapies.

In 2003, the government also developed the Comprehensive Plan for the Treatment Care and Support of HIV which takes into consideration the whole range of treatments and financial aid that will be allocated to people living with HIV/AIDS.

Director general of the National Department of Health (NDOH), T. D. Mseleku, said that transforming the SA healthcare system is not short of its challenges. "The government of SA developed a strategy called the National Strategy for HIV/AIDS 2000-2005, which looks at various aspects from research to prevention, health support, and traditional medicines and so on," said Mseleku.

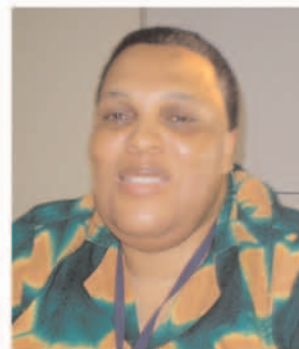
The battle is being fought in conjunction with various drug companies, both local and international, but Mseleku said the big multinationals need to be aware of the very particular market in SA. "The big challenge is to make sure pharmaceutical companies focus on research and development that really relates to the challenges of the south and that they start to address the matters that are really affecting our people," said Mseleku. "We don't want to simply be an extension of the northern market, we want innovative medicines for our most common diseases."

Bristol Myers Squibb (BMS) possesses a large global ARV franchise, but wanted an additional role to play in fighting the pandemic. BMS and its foundation commit around \$150 million to help women and children in Sub-Saharan Africa through its Secure the Future initiative.

It has also created the Pediatric AIDS Corps, a venture with Baylor College of Medicine in Houston, which will send 250 doctors to Africa over five years to treat AIDS children, and train local professionals. The valuable short term solution is aimed at treating the crisis while bridging the knowledge and personnel gap until local capacity can be developed.

GlaxoSmithKline (GSK), present in SA for over 100 years, has implemented its Global Access to Medicines Program which offers ARVs to qualifying groups at not-for-profit prices. In addition, GSK has issued five voluntary licenses to generics companies to manufacture, sell, import and distribute ARVs throughout SA.

Karim El Alaoui Mustapha, general manager Pharmaceuticals for GSK South Africa said voluntary licenses were an additional tool used to address the crisis. "GSK has been willing to discuss with all genuine partners on how to maximize affordable access to medicines in developing countries," he said. "But it is important to be realistic about the challenges and



**T. D. Mseleku Director General
of the National Department
of Health**

the benefits of licensing agreements. It is vital to choose the right partners. Licensees must be able to ensure sustainability of supply, that the medicines are used safely and that they can protect products against diversion."

**"We don't want to simply be an extension
of the northern market, we want innovative
medicines for our most common diseases"**

In an effort to ensure that ARVs intended for the neediest countries are not diverted towards developed countries, GSK recently differentiated its not-for-profit ARVs from the private sector tablets by changing the color coating from white to red.

Big local player, Aspen, has been involved with both GSK and BMS from the early days of voluntary licensing. Stavros Nicolaou, NAPM's vice-chairman and Aspen's senior executive in charge of strategic trade development, said the company jumped on the opportunity to secure ARV voluntary licenses as soon as they were granted. "Nobody had ever been granted ARV voluntary licenses before and doomsayers predicted we were crazy to have applied for them in the first place," said

Nicolaou. "It was probably fortuitous when we made this approach to the innovator companies as it was around the time that there was an out-of-court settlement between the multinational industry Pharmaceutical Manufacturers' Association (PMA) and the SA government." Aspen then started setting up other agreements with Boehringer Ingelheim, Merck and Eli Lilly, all in the AIDS/TB field.

Nicolaou said the SA health situation started advancing about four years ago when the market's donor fund segment started developing. "In the early days of AIDS the reliance was on ad hoc donations. It was very sporadic and there was no certainty or predictability." At a similar time, the Global Fund for AIDS, TB and Malaria (GFATBM) was created after the G8 meeting in Evian, France. As a result, founders and donor countries could start consolidating their efforts on a sustainable basis. This period also saw the beginning of the President's Emergency Plan for AIDS Relief (PEPFAR).

Although funding is the big issue, SA needs more than just money to fight the cause. In the Minister of Health's budget speech last April, the minister, Dr. Manto Tshabalala-Msimang, announced that the role of community health workers in particular is critical to providing support. "We will be strengthening the community health worker program and ensure that these workers are able to identify the healthcare needs of communities, refer people to relevant health and other government services and support those who are on treatment for TB, HIV and AIDS."

"In line with the president's directive in the State of the Nation address, and utilizing the significantly increased budget for HIV and AIDS for this year, we are implementing our Comprehensive Plan for Management, Care and Treatment of HIV and AIDS in its totality with much vigor. This comprehensive plan is centered around preventing the spread of HIV infection and improving the health system to enable us to provide a series of interventions aimed at improving the lives of those infected," she said.

One company concentrating on the TB side of the health crisis is American company, Eli Lilly SA, which was voted the best company to work for by the SA pharmaceutical industry. An agreement with Aspen has seen a transfer of technology for the manufacturing of antibiotics for Multi-Drug Resistant TB (MDR TB).

CEO Christopher Whitfield* said Eli Lilly SA launched a global MDR TB program about two years ago. "It was a program in collaboration with a whole host of individuals that we believe are important to deliver the right kind of health solution for MDR TB. It started with the WHO Greenlight committee on TB and we worked with them to find the high areas of need and the key components to

successfully treat patients.

"MDR TB is a type of TB that often develops in patients who do not complete the proper treatment for TB. Failure to contain MDR TB could result in the creation of a new, even more deadly strain of the disease. The goal of this initiative is therefore to train enough health personnel and increase the supply of critical drugs needed to treat MDR TB," added Whitfield.

Knowing the challenges of satisfying the entire volume required to treat the growing need for MDR TB drugs, Eli Lilly SA decided to partner with individuals, NGOs, and private companies throughout the world. Currently, Eli Lilly is establishing a Center of Excellence for the training of medical personnel in the treatment of MDR TB to curb any further spread of the disease.

Also in the fight against TB, Sanofi-Aventis SA, through its community aid project TB FREE, has signed a comprehensive agreement with the NDOH to offer support in the management and control of TB in SA. This is the first such agreement in the country and formalizes the Private Public Partnership already existing between Sanofi-Aventis, the

Nelson Mandela Foundation and the DOH.

John Fagan, General Manager of Sanofi-Aventis, said the company has a responsibility not

just to bring good research and development to SA but to also look after particular local needs. He says they have achieved this through a threefold objective: "A stepped up research and development program, a sharper focus on diseases like TB and malaria that severely affect South Africans, and a Corporate Social Investment (CSI) project that can improve the health of millions in this country."

A solution to the TB problem is on the top of Sanofi-Aventis' list. "It's a sad situation as 37 people die every day from this curable disease," said Fagan. "A lot of this is due to the fact that when the patients are feeling better, they stop taking the drugs. If you take your TB drugs for instance an average of 85% of patients will recover. As of today, many patients are still non-compliant on the drugs so the cure rate is only 45 to 50%. We are working with the NDOH to improve the compliance issue and most of that is being done by training people to go to the patients and observe them taking the medicines."

Fagan explained that the company has committed about \$15 million over five years, and together with the Nelson Mandela Foundation as the patron and the NDOH, training will be put in place to train 25,000 Direct Observation Treatment (TB DOT) supporters by 2009 (around 7,000 have already been educated). "In each nine provinces, we will establish a center which will train people, family or community members

**Around six million South Africans
are expected to die from AIDS-related
diseases over the next ten years.
Half a million are in dire need for of ARVs**

* Whitfield left Lilly at the end of January 2006

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In South Africa, the AstraZeneca clinical research department is a key drug development site and manages one of the largest pharmaceutical-development programmes in the country.

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* IMS data 2005



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who will go to the patients, explain what the disease is as well as the need to take the medication. And then we will also send mobile units or clinics to the rural areas to educate TB DOT supporters, and also track the recovery of the patients who have been taking the drugs.”

The Sanofi-Aventis factory in Pretoria contains a plant that is FDA approved to manufacture pyrazinamide, the basic active ingredient of TB products. On the research and development front, the company also has a laboratory which is

looking into moving TB products from single to four drug combinations.

Currently, SA is thought to have the highest incidence of HIV/AIDS and unmet need in the world. The government, NGOs and private companies, both South African and abroad, are fighting the good fight—but the end is still nowhere in sight.

Cheaper Healthcare Insurance Could Trigger Ethical Market Boom

One of the most critical issues facing the South African healthcare sector is the striking discrepancy between private and public segments, in terms of both facilities and funding. A perfect illustration of this: The South African private healthcare service is ranked fourth best in the world according to global consulting firm Monitor, while the public system ranks amongst the lowest according to the World Health Organisation.

According to the DOH, the public sector spends \$5.4 billion per year on 37.9 million people, while the private sector spends \$7 billion on just 6.9 million people, of which about three in four are white.

While the public sector is responsible for 80 percent of the population, the private healthcare sector, one of the most modern in the world, only serves the seven million South Africans who can afford medical insurance. In SA, health insurance plans are known as medical schemes. Three groups, i.e. Netcare, Afrox Healthcare and Medi-clinic divide an 80 percent share of the private-hospital market that accounts for 25,000 beds (around 20% of the country's total capacity).

This is an unacceptable situation in a country that vowed to eliminate the after effects of apartheid. The government regularly criticizes the private sector for not paying its contribution to the national effort, and for pointing out the increasing costs of medical schemes tariffs (driven by hikes in private hospital fees) and their unwillingness to develop

products catering to the lower end of the market. At a medical scheme conference, the Minister of Health, Manto Tshabalala-Msimang, called the system ‘unfair’ and pointed out that it needed “to be remodelled.”

The government hopes to use the buying power of the Government Employees

Stakeholders in the pharmaceutical industry are trying to find solutions to shift at least seven million patients from the public to the private system

Medical Scheme (GEMS) to temper the spikes of cost of medical schemes. Created in 2005, the GEMS plans on covering the 400,000 civil servants who are currently members of 68 existing schemes. It should become the largest in the country.

Tops on the cabinet's agenda is the introduction of Social Health Insurance (SHI), which should be funded by a mandatory tax levied on all employed residents of South Africa. Despite resistance from organized labor unions and fears that it could dent people's spending power, Tshabalala-Msimang says the SHI is a “priority for the government”.

A first step to the SHI, would be the implementation of a Risk Evaluation Fund, starting as early as 2007. It would aim to equalize the cost of providing prescribed minimum benefits (PMB), which are set by law. Schemes with a higher proportion of younger and healthier members will pay money into the fund, which will then be distributed to schemes with older, less healthy members.

Recognizing that the implementation of SHI could take years. The MOH has launched a broad survey to study the relevancy of a Low Income Medical Scheme (LIMS). It is targeted at low-income households with the aim of mapping the potential coverage and pricing.

The survey is coordinated by Jonathan Broomberg, who also happens to be the general manager of Discovery Holdings, the most profitable administrator of medical schemes in South Africa. Noting that “one of the most important problems of low-income families to access private healthcare is cost”, the survey intends to identify the barriers to low income participation in medical schemes. It also plans to develop appropriate policy options by addressing the feasibility of a different PMB framework and evaluate the willingness of suppliers to make products and services available at a lower cost to the members of LIMS.

Initial findings tend to show that with a revised set of minimum requirements, the minimum package could reach \$32, half the current market's cheapest offer. Broomberg points out that changing the PMB would require a change in regulation.

The survey is funded by various parties including the Pharmaceutical Manufacturer Association of South Africa, PMA. The organization, which consist of 23 pharmaceutical companies, accounts for roughly half the market share of multinational companies in SA.



Health and wellness for all

One of South Africa's top ten pharmaceutical companies and listed on the Johannesburg Securities Exchange, Enaleni Cipla Pharmaceuticals Ltd is one of South Africa's fastest growing pharmaceutical and personal care companies. It is also a contract manufacturer for international and local pharmaceutical and nutraceutical companies such as Merck Generics, Reckitt Benckiser SA, Unilever and Pharma Dynamics. Enaleni Cipla is also one of South Africa's largest local manufacturers of pharmaceuticals.

With the recent acquisition of Cipla Medpro, the Enaleni Cipla Group is the fifth largest pharmaceutical company by volume in South Africa and one of the largest tenderers of pharmaceuticals to the government market.

Marketing leading generics in the anti-retroviral, cardiovascular, respiratory, psychiatric and anti-inflammatory categories, combined with strong

black empowerment credentials and an AA rating from independent empowerment rating auditors Empowerdex, means Enaleni Cipla is well positioned to meet the South African Government's Health Care Charter criteria and contribute to achieving Government's objective of providing affordable healthcare for all. With one of the largest pharmaceutical sales forces in SA, the group has over 100 sales representatives detailing doctors and pharmacists. Enaleni Cipla offers competitive pricing, excellent service levels and has capabilities to offer internationally competitive **outsourcing, joint venture or tender partnership solutions** in liquids, tablets, capsules, creams, effervescent, powders and laboratory testing.

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A PLACE OF PROMISE

It is no surprise that pharmaceutical companies are interested in such initiatives, considering that the number of people who benefit from private health insurance has hardly increased in a decade. The industry, which has had to make enormous efforts to reduce prices, would welcome such an initiative.

For Dr. Guni Goolab, the president of PMA and CEO of Astra Zeneca in SA, this is the correct path to explore: "If more people come into the insured environment, through initiatives such as the Government Employees Medical Scheme and the LIMS project, then this will nearly double the number of patients within the insured environment over the next five to ten years. I can only see that as a major opportunity for all healthcare stakeholders," he explains.

Nevertheless, Goolab warns that very little can be done as far as providing cheaper medicine to any of these schemes, explaining that several price reduction policies have already daunted the capacity of the industry to offer better prices: "The expectation that there will be further substantial price reductions shouldn't be there. We have already reduced our prices through the Single Exit Price process, there hasn't been a price increase for almost three years and there will again be a further price adjustment," he explains, pointing out that patients are already benefiting

from much cheaper prices: "we estimate that as a result of these changes, patients will be 35 to 40 percent better off."



Dr. Guni Goolab, president of PMA and CEO of Astra Zeneca SA, hopes the Government Employees Medical Scheme and the LIMS project could double the size of the private market"

A self-defined product of SA's Employment Equity (the local equivalent of affirmative action), Goolab, a medical doctor, is in a good position to understand both the governmental positions and the exigencies of multinational companies.

"I try in some way to bring together the two very different perspectives," Goolab explains. For example, he believes that the government and the multinationals should try to cooperate on R&D: "We already have a very strong R&D base, so we should specialize

to stay competitive, he says. "The pharma industry should work in partnership with the government and academic institutions to select two or three therapeutic areas and turn SA into a world class center in these areas."

According to Goolab, this is essential since it "also plays an essential role in keeping the high-caliber researchers in the country." He says that as far as Astra Zeneca is concerned, every product launched since 1999 has been researched by local experts, one way or another. Astra Zeneca SA manages the largest, single pharmaceutical development program in Sub-Saharan Africa and in 2003 was voted the most efficient clinical development organization within the group.

Countries with the highest reliance on PHI (Private Health Insurance) measured as a % of total health expenditure.

Country	%
South Africa	44.3
Uruguay	36.8
USA	34.8
Namibia	32.1
Zimbabwe	26.7
Netherlands	24.9
Chile	23.1
Brazil	20.8
Canada	19.8
Switzerland	18.8

Source : World Health Report, 2002, quote in Smith (2005)

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Phelophepa : Healthcare on Track

After apartheid fell more than a decade ago, thousands of SA's poorest, predominantly black, rural citizens started receiving essential primary medical care for the first time. For a decade now the Phelophepa train of hope has been spreading hope through the poorest and remotest regions of SA. "In the previous regime, all the money was allocated to a small percentage of the population," explains Lynette Coetzee, managing director of the Phelophepa project.

Phelophepa, a hybrid word derived from local languages, Sotho and Tswana, literally means good, clean health. Coetzee gets emotional when she talks of the start of the project recalling how stumped she was by what she discovered when she started on the train to the back of beyond. "None of us knew what the backlog really was," she says admitting that the train also acted as an eye opener for her.

The psychological and emotional impact of having white doctors healing black people for the first time in their lives and treating them decently, might be as important as the healthcare they received. This would have been unbelievable to many only ten years back.

Transnet Limited, SA's largest logistics company, devoted \$2.4 million in capital funds to set up the train. The Transnet Foundation now provides about 58% of the train's funding. Phelophepa receives no government financial aid so the remainder of monetary support comes from private local and international contributors and corporate donors (via money or goods) such as Roche S A.

Roche has been on track with Phelophepa since its earliest days. Maturin Tchoumi, the Cameroon-born CEO of Roche SA, knows the rural existence well, having grown up in a modest farming family. Tchoumi says he recognises that SA's pharmaceutical industry is in a unique position compared to the rest of the world. "We have similar challenges to those faced by wealthier, developed countries, but we also have to address challenges that arise within developing countries, such as lack of infrastructure to deliver healthcare

or lack of resources to purchase medicines.

As a socially aware company, Roche considers its participation in the program an appropriate responsibility for any multinational company operating in post-apartheid SA.

"When you are a successful business organisation, as we are, you are responsible and accountable to the community," says Tchoumi. We are very aware of this and are very serious with our social responsibility. That's why we are involved with Phelophepa."

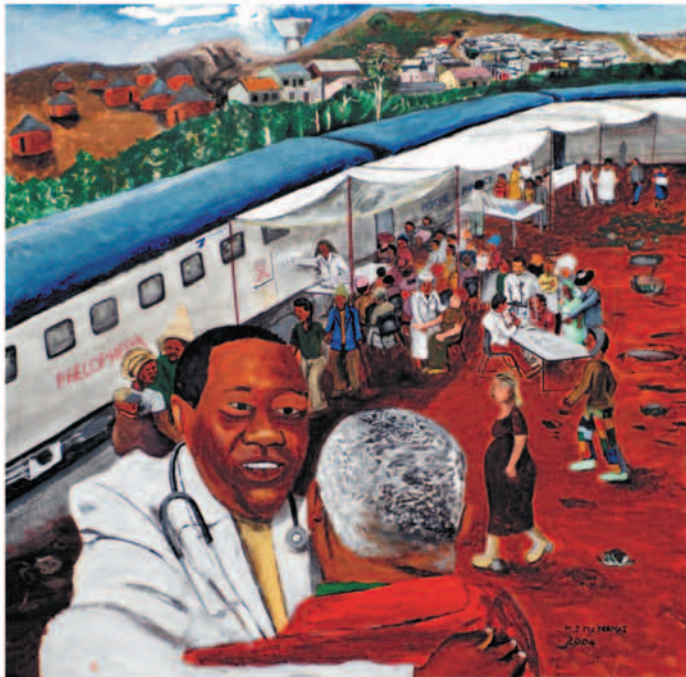
Roche's involvement with Phelophepa is genuinely altruistic: Despite the logistical difficulties of accessing patients an average consultation on the train costs only about 80 cents. "The beauty

of Phelophepa is that there is not a single product of Roche's sold on that train," says Tchoumi. Our commitment is with making an impact by bringing primary healthcare services to SA rural populations."

Originally, Phelophepa was an eye treatment centre on tracks but it quickly developed into a comprehensive primary health care facility with 16 compartments each dedicated to a speciality and equipped accordingly. Patients now receive general medical care as well as specialized dental and mental services. The latter, due to its relative invisibility, has long been a forgot-

ten area of medicine in poorest Africa. Many patients treated by the Phelophepa psychology unit are unaware of their mental health problems or the fact that care is available.

As demand for specialized treatments in isolated areas persists, the Phelophepa phenomenon is continually growing. The train now visits nine provinces and covers approximately 15,000 kilometres from January to September each year. Sixteen permanent staff members reside on the train. They are assisted by dozens of students who each spend at least two weeks working and sleeping on board. At each stop, locals are hired temporarily to provide essential services such as cleaning or interpreting. Around 40,000 patients are treated for a broad range of medical conditions each year.



Painting for the Phelophepa art competition

DIFLUCAN PARTNERSHIP PROGRAMME - SOUTH AFRICA

In December 2000, Pfizer first launched the Diflucan® Partnership Programme (DPP) with the Ministry of Health of South Africa (SA). The programme makes the anti-fungal drug Diflucan® available free of charge for treating patients presenting with two HIV/AIDS-related fungal opportunistic infections, namely, Oesophageal Candidiasis and Cryptococcal Meningitis.

Implementation and Management

Following the launch of DPP in South Africa, in 2001 the Minister of Health, Dr Manto Tshabalala-Msimang, formed a Ministerial Working Group (MWG) to oversee and coordinate the activities of the programme. The MWG is coordinated by the National Department and is comprised of coordinators from 9 Provincial Health Departments, Correctional Services, Military Health Services, National Hospital Laboratory Services, NGOs and Pfizer. Each province implements its programme locally; ensures effective rollout and scale-up of the programme, and reports to the MWG.

Drug Supply and Distribution

Provincial depots order the donated Diflucan® directly from Pfizer, store and supply participating facilities as required. To ensure that drugs safely reach designated facilities, Diflucan® is distributed as a controlled substance under the South African Pharmacy Act, which entails tight controls on handling, storage, prescribing and dispensing.

How to Access the Programme

Each province implements and manages its programme. Requests and applications by government and NGOs facilities to

access DPP are handled through coordinators in each province. Every application and request is reviewed by provincial departments to ensure compliance and meet programme requirements and objectives.

Milestones Reached

453: sites dispensing Diflucan® free of charge. SA accounts for 42% of all the sites globally.

7 million: free doses of Diflucan® donated by Pfizer to the Ministry of Health and participating nongovernmental organizations.

100 000: patients treated for these two life-threatening fungal opportunistic infections at participating sites.

16 400: healthcare professionals trained in the diagnosis and treatment of these opportunistic infections.

Materials: training material developed and patient information leaflets produced in English, Zulu, Xhosa, Sotho and Afrikaans.

Programme Expansion

Based on the success of the programme in SA, in June 2001, Pfizer extended the programme to all developing countries with HIV/AIDS prevalence more than 1%. Today, 42 developing countries in Africa, Asia, Latin America and Caribbean are participating in the Diflucan Partnership Programme.

For more information:

website: www.diflucanpartnership.org

email: lebogang.taunyane@pfizer.com



Post-Apartheid Rules Change the Face of Industry

Already heavily regulated, the South African pharmaceutical industry is in a unique situation due to the government implemented Black Economic Empowerment Act (BEE). The BEE, introduced in 2003, has changed the face of business ownership in post-apartheid SA. The Act promotes the economic empowerment of black South Africans of all ages regardless of sex, disability or locality through diverse but integrated socio-economic strategies.

One successful home-grown company has taken the changes in its stride as it continues to expand market share at home and abroad. In just three years, Enaleni Cipla has reached annual revenues of \$117. The company employs more than 300 people, 95 percent of whom are black. Many of them are shareholders.

The Enaleni story began in January 2003 when employees at the Durban Reckitt Benckiser SA manufacturing plant were facing retrenchment. The middle-management approached Edwards and another well-known entrepreneur, Stan Whitfield, to organise a buy-out and Enaleni was born.

Enaleni immediately proved itself as a serious player by successfully winning against stiff competition the rights to produce Reckitt Benckiser's Dettol, Disprin, Gaviscon and Senokot brands. And starting out with just that one contract manufacturing client, RBSA, the Enaleni executives created an effective operation that soon provided outsource manufacturing solutions to other leading multinationals.

Over the past three years, Enaleni family has grown rapidly by buying up brands and acquiring companies. Enaleni offers small local companies an opportunity to join hands with the strong BEE manufacturer. A partnership with Enaleni will help the smaller organisations grow within the government's Health Care Charter, which calls for increasing BEE involvement.

"With the high barriers to entry in SA and the regulation procedures, we knew it wouldn't be easy," recalls Trevor



Trevor Edwards, CEO, Enaleni Cipla

"We have a very good business model that happens to be SA's leading empowerment pharmaceutical business"

Edwards, Enaleni's Chief Executive Officer.

Enaleni recently acquired FirstPharm Pharmaceuticals and Cipla Medpro the subsidiary in South Africa of India's generics giant. The Cipla Medpro acquisition catapulted Enaleni into SA's top ten company according to Edwards. The merger gave Enaleni a stronghold in SA's generics business as well as the OTC market, and eventually the opportunity to grow its own brands throughout Africa. Edwards is confident that Cipla Medpro's product lines will significantly strengthen Enaleni's already significant (\$11 million) government

contracts platform.

We will also be looking at converting our current facilities to achieve FDA approval to allow us to provide ARVs to state and private markets." He adds.

Edwards, is proud of the company's recognition as an empowered enterprise but admits there is still a lot of work to do to spread Enaleni's wings even further. "We have won many awards for being so progressive but you don't build a business on empowerment."

"Our strategy is not to buy companies, close them down and integrate them into our business. We keep the management on and welcome them into our business as partners and give them the platform and the critical mass to compete." he explains

"We have a very good business model that happens to be SA's leading empowerment pharmaceutical business. That positions us in the best place of all the pharmaceutical companies in SA. With the Enaleni's BEE credentials, the opportunities are incredible."

However, the trend of buying up big will not last forever. "In SA we have just about finished acquiring businesses," said Edwards. The next step for Enaleni is to prove to the market that it has the capacity to mature alongside the developing SA pharmaceutical industry.



(From left) Enaleni directors Stan Whitfield, Dave Wolfson, S'bu Luthuli (non-executive chairman), Dali Tambo, Pamela Pillay, Umesh Parusnath and Maxwell Sithole at Enaleni Cipla's Johannesburg Stock Exchange AltX listing in June 2005

Bright Prospects for Generic Market

In South Africa, only around seven million citizens have private health coverage and the remaining 38 million, many of whom are plagued by chronic diseases such as HIV/AIDS, malaria, and TB, do not have the financial means, so finding low-cost medication alternatives has become crucial.

With rising global healthcare costs, generic medication is the only realistic way for the majority of impoverished South Africans to access safe and affordable treatments.

Responding to the desperate need for inexpensive medicines, the SA government introduced legislation in 2003 encouraging the use of generic substitutes in preference to patented products. The Department of Health's initiative urge patients, wherever possible, to use the cheapest products available. The legislation also obliges pharmacists to offer the consumer a generic substitute for prescriptions when one is available. Doctors, however, may indicate when a generic product is not acceptable.

Despite the money-saving move, generic use in SA is still disproportionate on a world scale compared to Europe or the US. Estimates suggest an increase of market share from 23.5% today to around 35 percent in value terms by 2009 with spending reaching \$1.9 billion at consumer prices.

With significant investment in generic research and development by local companies, and outside interest from the international market, the future looks bright for SA generics. Generics are slowly getting where they are needed, but the path is not obstacle free. An initial hurdle has been distrust and fear. Opinions are changing, but many still see generics as inferior.

SA's famously long registering delays (sometimes up to two years) have been widely criticized due to the desperate need for some products, particularly ARVs. Thus registration also created an

invisible entry barrier. Nevertheless delays vary according to the product but for some high-necessity medications, or those just out of a patent, there is a 'fast-track' facility.

SA generic prices have been under debate for several years and are continuing to fall. In 2004, the National Association of Pharmaceutical Manufacturers (NAPM) commissioned a study revealing average prices for 38 out of 42 generic molecules sold in SA cost less than their international counterparts in a seven-country average.

The NAPM mainly represents SA generic pharmaceutical companies and

The share of generics could rise from 23.5% to 35% before 2009

is focussed on improving the market share. NAPM president, Muhammad Bodhania is quietly confident: "The way we promote (generics) is by increasing their usage in value terms. One way of doing this is by increasing the efficiency of registering generics faster."

The NAPM's stance is to encourage innovation and patent protection to maintain the pipeline for generic products. "The current intellectual property law indicates that generics companies are allowed to develop products while the patent is there, but can't commercialize them. We strongly advocate this position".

Globally, a large number of blockbuster drugs have recently come off patent. The trend is expected to continue until 2008. According to FDA, patents on 200

brand-name drugs will expire in the coming years.

This is also the situation in SA, which therefore has attracted interest from outside companies.



Paul Anley, CEO, Pharma Dynamics:
SA's fastest growing
pharmaceutical company

Satish Reddy, managing director of Dr Reddy Laboratories, India says: "As a generics company which has a rich pipeline and who is able to develop products very aggressively, we feel this is a market where we can really make a difference."

The intellectual property transfer that the multinational giant Merck KGaA of Germany underwent with Aspen has made a significant mark on the SA scene. When it comes to generics, Merck KGaA has one of the best development pipelines worldwide.

Merck SA managing director Deon Vos describes the relationship with Aspen as significant for their future in SA. "It is always good to partner with strong organizations that bring you greater commercial value, especially in the generic business."

Vos explains that while developing generics in SA is vital, Merck SA will not restrict itself. "We don't want to be seen as a generics company, and we don't want to be seen as a purely prescription company either because there are two clear distinctions. We want to be seen as a healthcare company that services the needs of a broader population in SA."

The trend of locals uniting with foreign entities has never been stronger as SA pharmaceuticals seek support in the competitive generics game.

Sekunjalo's joint venture with Indian generics outfit, Unichem will see the company grow, and more significantly, help fast-track their generic dossiers.

While the strict guidelines of the government's Health Care Charter (HCC), including the unique BEE requirements, may have some companies overwhelmed others see it as a necessary social responsibility. "We have to think about the bottom of the pyramid, where the majority of our people are in Africa," says Muzi Nkosi, CEO of Sekunjalo Health Care.

Sekunjalo has several subsidiaries: In pharmaceuticals (Sekpharma), medical diagnostics (Rapimed), medical disposables (New Promex Corporation) and health IT (Health Systems Technologies). As CEO of the pharmaceutical branch, Nkosi feels profit margins need to be relativized to the current health situation. "Innovators spend a lot in research and development and generics follow. Therefore, ethical and generics can't be similarly priced but ethical manufacturers can't be greedy in raking in the profits at the patient's expense."

Paul Anley, CEO of one of SA's fastest growing pharmaceutical companies, Pharma Dynamics, says their relationship with leading international generic manufacturers is vital. "We believe the pharmaceutical market is globalizing very rapidly and the economies of scale in pharmaceuticals largely outweigh any cost benefit there might be in terms of

local manufacture."

The SA generics business differs to that in the US due to its area of branded generics. Pharma Dynamics is strongly-branded, spending a lot on advertising and marketing. Anley says this is an important aspect to the market. "A lot of doctors are supporting generics, but they support them by brand or through the quality image of the company."

Currently, when available, only generic

products are used in SA public hospitals, making the state health system the largest user of generic products in the country. Eighty percent of all state-issued medications are generic. But overall, the largest slice of the pharmaceutical pie is still the private hospitals.

One company that is managing to cater to both the public and private sector is Hexal-Sandoz. Despite the fact that 80 per cent of the SA generic market is



Muzi Nkosi, CEO of Sekunjalo Health Care

"We have to think about the bottom of the pyramid, where the majority of our people are in Africa"



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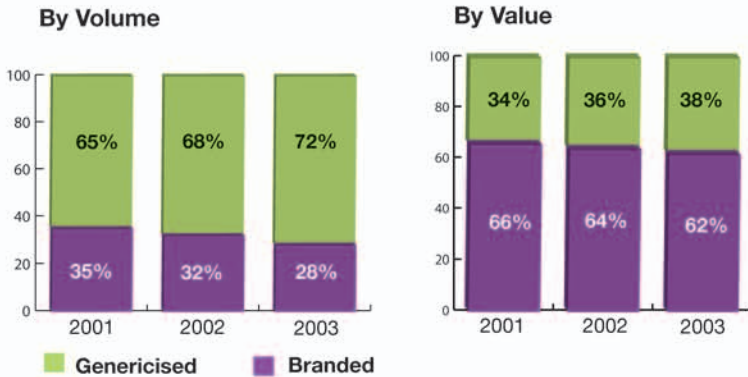
dominated by two local champions Lynton Lomas, CEO of Hexal-Sandoz SA is confident that there is room for everyone in the future.

“The market is still very ripe for us to run two brands very successfully,” says Lomas. “Sandoz brings to the table huge expertise in tender business including TB, where they have been very successful. Hexal has been very successful in first-to-market products, far in excess of what our competitors have had and has moved into the speciality market of upper-end generics.”

Overall, the SA generics market is still dominated by the local giants, Aspen and Adcock. The strong relationship they already have with local pharmacists and doctors, added to a slow registration process that favors companies already on the market mean outsiders are hit with obstacles upon entry to SA. Nevertheless, other players are gaining momentum and as multinational corporate buyouts and mergers continue, the SA pharmaceutical field is starting to take a new shape.

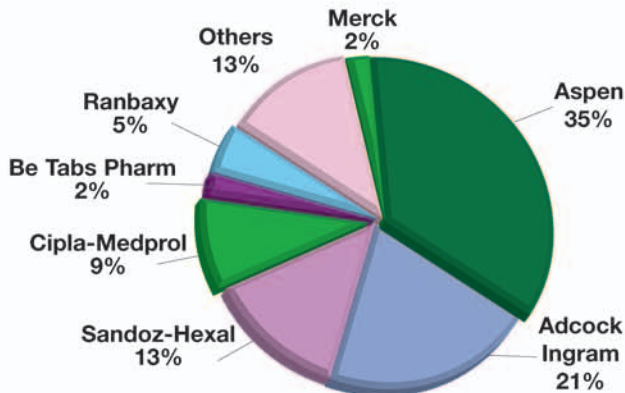
“Genericized” VS. patented drug utilization

(Top 15 therapeutic classes)



Adapted from the Pharmaceutical Task Group (PTG) submission to the Medicines Pricing Committee, April 2004
 Source : IMS SANDS (SA database) Dec 2003
 It should be borne in mind that the “genericisation” index is made up of :
 (A) sales of “true generic” drugs (generic copies)
 (B) off-patent products, that continue to be sold under established brand names by the inventor companies after expiry, competing with generic products.

Private generic market to June 2005



Source: IMS

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Tiger Roaring in Lion's Den

For the South African pharmaceutical industry one of the major issues is affordable healthcare for the three quarters of the population who currently have little or no access to it. In addition to the remoteness of rural communities and tight industry regulations, pharmaceutical companies must battle with consumer confidence when it comes to low-cost medicines—in particular, generics.

Now that doctors and pharmacists have begun to recognize that generics are therapeutic, scientific and pharmaceutical equals to the original drugs, patients are following suit. Government legislation in SA encouraging generic substitution, the implementation of prescribed minimum benefits by medical schemes, and the dire need for ARVs in Africa means affordable medicines are highly sought after.

One provider of such affordable medicines is Tiger Brands, through its subsidiary Adcock Ingram. Adcock Ingram's generic brand, Adco, has grown to become a strong competitor in the market and Adcock has been very successful at establishing this brand by leveraging the brand heritage of Adcock Ingram as a leader in OTC products (21% market share in June 2005) and the relationship this created with pharmacists. As a result, its portfolio of chronic medicines has fully benefited from the advent of the compulsory generic substitution where pharmacists have a stronger say in what drug to dispense.

For Dr. Jonathan Louw, Adcock Ingram managing director, branding has played a critical part in their success alongside the extensive range of products. "It's

unusual to find markets where two generic brands are among the top sellers

first-to-market generics—believing that targeting blockbusters coming off patent

“On a pure price platform, it has been difficult to compete in Africa, but if there is one thing where we are very competitive, it is in our quality”

in the country, yet we have two Adcock products in the top ten. This illustrates

should generate a strong growth. “Being a heritage company, we have developed and successfully launched, a number of ‘firsts’ for the SA market,” he said. This strategy seems to have paid off, and according to IMS data, following the acquisition of Parke-Med two years ago Adcock now holds a 21% (May 2005) market share of the private generic market—a nine-point gain in the past two years. On the other hand, these products are at risk of intense competition which could impact margins negatively.



Dr. Jonathan Louw points out the role of branding in Adcock Ingram's success in the generic market

the strength of our branding and the importance of generics in this market,” boasts Louw.

He adds, “The impetus in the business has obviously been on brand building and providing affordable medicines to the people of SA. We are also raising the awareness of generics, letting people know that there are affordable alternatives available.”

Louw points out the company's strong pipeline and its strategy in terms of launching new products—specifically in

In Louw's four years as MD, the company has extensively restructured the pharmaceutical business, focusing on strengthening the pipeline of new products by investing in local research and development while forging strong alliances with international partners. Adcock also boasts 40 international licensors, owns four world-class manufacturing facilities (including the country's largest liquid facility in SA) and a sophisticated self-owned delivery system. Adcock is the only SA company to have its own countrywide distribution function and was also the first SA pharmaceutical company to secure SA's Medical Control Council accreditation for a research and development facility.

According to Louw, manufacturing many products locally leads to a higher market share, as Adcock Ingram can



then better control supply chain quality. Adcock also looks with interest at continental market developments that could generate export potential: “the big opportunities are right on our doorstep in Africa. We want to supply affordable medicine to sub-saharan Africa.”

But he also acknowledges that it is sometimes difficult for African manufactured products to compete with cheaper imported drugs: “On a pure price platform, it has been difficult to compete in Africa, but if there is one thing where we are very competitive, it is in our quality. We are also very well-priced.”

Nevertheless, Adcock is not yet active in the promising ARV segment and is probably two years away from having registered products. Louw believes that this should not be too much of a problem in the long run and explains that Adcock has elected to develop its own ARVs. “We are developing our own products to world class standards and these will be locally manufactured in our facilities.”

Adcock Ingram was the first SA pharmaceutical company to secure SA’s Medical Control Council accreditation for a research and development facility

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Indian Companies Set Eyes on SA Market

The US is presently the largest importer of Indian pharmaceuticals, accounting for 17 percent of total exports. However, recent sharp falls in generic drug margins in the US has meant Indian exporters will need to look elsewhere.

Recent changes in legislation mean cheaper branded medications are beginning to flood the SA market, and the huge Indian giants are joining the flow. Logically, SA appears to be the perfect

Reddy, son of the founding Dr Reddy says he is not threatened by the dominance of local players and is confident there is a place in the market for them. "Being based in India gave us an advantage regarding a cost point of view and at the same time we had the great benefit of having access to a highly scientific population. We have the best of both worlds; the best of the skills base, we have cutting edge research and a very productive pipeline."



Vikash Salig, executive director, Venturepharm

Satish Reddy, managing director and COO, Dr Reddy's Laboratories

Dr. Reddy of India and the JJ Group of South Africa created Venturepharm to capture some of the fast growing generic market

destination for India's export drugs. Although imports of Indian products only represent three percent of total imports in value, currently, Indian companies, according to a recent industry study released by the Assocham in India, could be well-placed to capture as much as 50 percent of the SA generic market which is estimated to hit a value of around \$2.1 billion by 2010.

A recent merger between well-known SA group Enaleni and Indian pharmaceutical firm, Cipla has already increased the latter's SA market share from seven to 11.6 percent in two years. Other Indian-based companies are following suit.

Satish Reddy, managing director and COO of Dr Reddy's Laboratories, an emerging global Indian pharmaceutical company with operations in more than 100 countries, says Dr Reddy's is about getting into markets early. "In the past five years since we've been focusing on the key markets of the world, SA happens to be one large market where we want to be present."

As an outsider, Dr Reddy's did not have specialized knowledge of the SA market, but used its expertise to create Venturepharm in conjunction with the JJ Group of companies (a prominent broad-based, black-owned SA investment and management company).

Dr Vikash Salig, CEO of Dr Reddy's in SA, and executive director of Venturepharm, says the company understands the significance of the BEE and felt it was important to unite with a black-owned company.

"The SA pharmaceutical industry has traditionally been a white-dominated sector, both from an ownership and employment perspective. There is an existing infrastructure and network of people that is difficult to break into."

But he says that SA should look towards Asia as a training ground for the pharmaceutical industry. "India and China are leading the world in terms of generic pharmaceuticals so they could be good training centres for SA to learn on site and come back with much needed expertise."



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South Africa, Really a Regional Hub?

The SA pharmaceutical industry has no rival its region, neither in terms of quality nor quantity. Domestic production meets 60% of the demand, but an extremely small share of prescription medicines are produced locally. Besides, the SA industry is skewed with the virtually non-existent manufacturing of APIs, which are limited to a single company (part of the Aspen Group) with a limited range of products. Although the formulation of medicine is well established it is often plagued by an underutilized production capacity. Most formulation plants in SA operate at 50% of capacity or even below.

Worse still, SA has had very little success in the global race for foreign direct investment against countries such as Puerto Rico, Singapore or Ireland. The general trend over the past ten years has been the scaling down of manufacturing operations in SA. According to the Pharmaceutical Manufacturers Association, 34 manufacturing sites were closed between 1994 and 2004.

For example the production of human-grades vaccines was terminated in 2000, for economic considerations and due to the obsolescence of the technology used. Nevertheless, this could change in the future as the government has joined forces with private partners in an attempt to reestablish the capacity to manufacture vaccines through the Biologicals and Vaccines Institute of Southern Africa (Biovac). Selwyn Kahanovitz, CEO of Biovac, expressed his enthusiasm in seeing the public private partnership reaching its goals: "Vaccines are truly the cornerstone of any public health program," he said adding: "They are responsible for saving more lives than any other technology."

For Dr. Rob Davies, deputy minister of the department of trade and industry (DTI), SA offers many advantages for potential investors who wish to establish a manufacturing base: "the infrastructure is attractive; we have world class finan-

cial services, protection laws for investments, a credible court system, international recognized legal procedures and higher standards than many developed countries."



**Rob Davies, deputy minister,
department of trade and industry**

"The infrastructure is attractive; we have world class financial services, protection laws for investments, a credible court system, international recognized legal procedures and higher standards than many developed countries"



**Richard de Chastelain, general
manager, Bayer HealthCare**

"It has become more efficient to import drugs, which is a pity because it means a lot of jobs are lost"

Davies could have also mentioned the world's cheapest electricity and region's largest market, but truth is that the development of both a manufacturing and an exporting hub from SA are mitigated.

Richard de Chastelain, general manager of Bayer HealthCare in SA, regrets this

situation: "One of the sad things is that many multinationals do not produce here any longer. 10 or 15 years ago there were 30 manufacturers amongst the multinationals, and today there are only 7."

"The main reason why companies have scaled down their production facility is the cost and the barriers of entry. It has become more efficient to import drugs, which is a pity because it means a lot of jobs are lost," laments de Chastelain. Although it still produces ethical veterinary pharmaceuticals locally, Bayer was one of the companies to shut down its facility and is now sourcing all its OTC and pharmaceutical products directly from Germany.

De Chastelain also blames the divergences that often erupt between the Department of Health (DOH) and multinational companies: "the DOH appears openly hostile to the multinationals. It is essential they appreciate the value of the drugs we provide and the role we play in healthcare across the continent. The companies that invest here need to know that they are welcomed accordingly and not feel threatened by accusations of excessive profiteering, particularly in the private sector where making profit is the rule." He also pointed out the negative effect that mandatory generic substitution policies might have had on investment by multinational, calling it a "disincentive".

Can a country that merely accounts for 0.35% of the global pharmaceutical market by value really become an attractive destination for FDI ?

Noel Guliwe, CEO of Novartis SA, summarizes the issue very well: "The SA industry contributes to less than 1% of the global industry; our importance in size has also decreased with the implementation of the single exit price policy. To see more investment coming in, the volumes need to be increased."

One of the few black South Africans to

head a pharmaceutical company, Guliwe fears for his country's ability to face global competition: "SA is important regionally but cannot compete with countries like India. In order to be competitive we need to upgrade our level as a country and as a region."

While many companies were shutting down their facilities in SA others decided, on the contrary, to invest more in production capacity. The most significant recent investments will come from Aspen and their new \$ 30 million oral solid dosage plant, and an upcoming \$ 18 million facility to manufacture anti-TB antibiotics in Port Elizabeth. Merck Sharp & Dohme spent \$8.1 million to upgrade its Midrand facility, Roche has devoted \$18.3 million to expand and upgrade its Isando plant where it plans to produce an anti-malaria drug, Fansidar, for the global market. Finally, Pfizer has outlaid \$15 million since 1998 to upgrade its Cape Town plant.

For Richard Paulson, CEO and country manager of Pfizer in SA, the Cape Town manufacturing facility is a "point of pride", the culmination of fifty years of growth that have transformed a relatively small operation devoted to distribution and sales, to a completely integrated research-based unit.

Though it is a fact that SA only accounts for about 0.2% of Pfizer global sales, Paulson stretches the importance of the Cape Town "world-class manufacturing facility" by affirming its "global mandate", with drugs manufactured in SA and exported "throughout Africa and around the world."

Paulson is convinced despite a sometimes challenging market SA is a good place to invest: "In this complex market, it won't be always easy, but it will be rewarding. This country will continue to evolve and its market will continue to grow. "Why wouldn't we continue to invest and grow our manufacturing capabilities here? SA has a talented and educated workforce that is growing more impressive each year," he concluded.

This year Pfizer should open its new

regional headquarter for pharmaceutical and animal health for Southern Africa in Johannesburg, while the coast city of Cape Town has been selected as the future head office for Consumer Health for all of Africa and Turkey.



Chirfi Guindo, president, IMSA and managing director, MSD SA

"With our manufacturing capacity we have the capacity to export to other African countries. But for this SA and the region have to open existing deadlocks"



Richard Paulson, CEO , Pfizer SA

"Why wouldn't we continue to invest and grow our manufacturing capabilities here? SA has a talented and educated workforce that is growing more impressive each year"

MSD is taking a similar stand according to Chirfi Guindo: "We have decided that despite existing issues, SA is and would become a strategic country for us." Although he believes in SA potential to become a manufacturing and export hub for the region the managing director of MSD SA and president of the Innovative Medicines South Africa (IMSA) points out serious issues hampering such a development: "With our manufacturing capacity we have the capacity to export to other African countries. But for this

SA and the region have to open existing deadlocks."

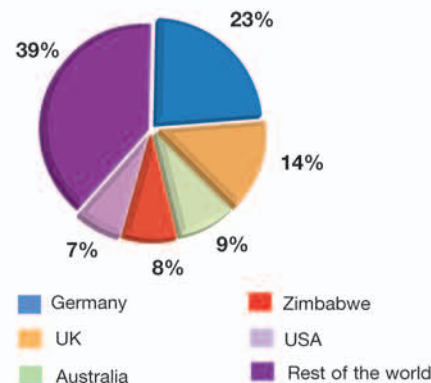
According to Guindo, the number one problem is registration of new medicine which he complains takes "far too long." For example, it took 18 more months to register Stocrin 600 in SA than in Kenya. "This is costing SA investments jobs and export revenue. I believe that if this problem could be solved we could double the volume of exports to other African countries," he said.

"But a necessary first step is definitively to increase the local market; this can only be done by boosting the number of people who have access to innovative medicines in SA. Today only seven million people have health insurance, this is far too little and could easily be doubled," he added.

Finally Guindo wishes that Southern African Development Community (SADC) harmonizes their registration procedures as did the European Union for example, i.e. alleviating the administrative burden of registering drugs in each country.

Despite a decline in exports to Zimbabwe, which used to represent up to 30% of SA drug exports, there has been a boom since 1994 from a \$10 million to just under \$90 million in 2003, and South African manufactured products are sold all over the world.

Exports in 2003



Source: IDT Economic database, based on SARS trade data.

Aspen is Spreading its Wings Across the Continent

Internationally accredited by WHO and MHRA, Aspen has made its global mark by becoming the first generic anti-retroviral (ARV) producer in the world to receive tentative approval from the FDA. When The Clinton Foundation was on a global search for cost-effective manufacturers of ARVs, it found three; two in India and Aspen. As the first generic supplier under the PEPFAR program, the generics giant will receive more than \$15 billion.

Given the gravity of Africa's health crisis, many people could simply not afford to receive HIV/AIDS treatments. According to Stephen Saad, Group Chief Executive of Aspen Pharmacare, the severe burden on SA's healthcare system would have been so extreme that government funding would have been drained. "When you look at SA's mortality rate, it has doubled in the last 10 years, simply because the poor couldn't afford drugs," Saad says. "HIV/AIDS is the worst disease we have ever faced and until we get a vaccine, which is the ultimate hope for the disease, generic ARVs are the only answer." Saad points out that the price of ARV generics is sometimes up to 98 percent cheaper than prices charged by multinationals in the USA.

According to WHO statistics, seven sub-Saharan African countries make up 43 percent of the world's population infected with HIV/AIDS but only 8 percent of sufferers are receiving ARV treatment. But Saad believes the situation might change rapidly as the funds are now getting to where they are needed: "Throughout Africa, donor funds are finally coming through. The money was there before, but it was spent on infrastructure and coming up with a plan. Now that all that's in place the donor funds are dealing with the huge demand for ARV. It is very difficult to forecast

what the future demands may or may not be."

Saad maintains that when it comes to ARVs, he has already succeeded in getting patients to swap to generic treatments: "The minute you have AIDS, you're not going to want to swap medicine, I promise you. Yet, thanks to our reputation, we managed to achieve generics substitution."

But he admits that Aspen did benefit from these developments: "The situation has certainly internationalized Aspen and put us on the map much faster than I had planned. It has opened a lot of opportunities for us." He also ultimately admits that the field of ARV generics will never be a big money-maker. "Anybody entering this market needs to understand they're not going to make a lot of money," Saad said. "We depend heavily on the SA government. If we don't contribute to HIV, AIDS, MDR and TB then what's the point in doing business in SA? There are more profitable areas where Aspen could spend development money. As long as we don't lose money, we will put our development in. "It has been very challenging."

Saad has the future mapped out for Aspen, the southern hemisphere's largest manufacturer of pharmaceuticals and a



Stephen Saad, group chief executive, Aspen Pharmacare

"If we don't contribute to HIV, AIDS, MDR and TB then what's the point in doing business in SA ?"

Fame in Monte Carlo, Saad has been continually applauded for his innovative ideas.

A market leader in South Africa and the only producer of API, since the take over of First Chemical Corp., Saad's vision for Aspen is to grow manufacturing capabilities to cater to international business while meeting the challenges of ARV

distribution.

On the domestic front, Aspen manufactures more than four billion tablets and capsules for SA each year. With an overall population of around 40 million people, Aspen supplies about 100 tablets per South African annually.

The proud South African with Lebanese



Aspen's new Oral Solid Dosage facility in Port Elisabeth

roots sees a growth in Africa beyond already developed markets. "We will first target our neighbouring countries and then move up to Kenya, Tanzania and Ghana," says Saad. "Eventually, I would like to break into the French African market which is very different to English-speaking Africa."

"I find Europe a lot less interesting than Africa," he said. "Europe is fully developed. Everywhere you go, you meet competition or regulation and I don't know how one would show a sustainable and decent growth rate in a European economy in the long term. In Africa, things are improving every single year. There is a very real opportunity."

The unknown frontiers of developing Africa might be risky, but it is a chance he is willing to take: "I absolutely believe it's a mindset," says Saad. "You've got to say that you want to compete and then you've got to drive your business very hard down that line." He admits that breaking into the African market is tough: "We're going to just keep plugging away. Like anything in life, if you're a pioneer you have a bigger chance." Despite the possible risks in the international market, Aspen can take refuge in Aspen's success stories in Australia and the UK.

Answers



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Answers That Matter.

Rainbow Dermatology

Currently celebrating its tenth year in South Africa, France-based Galderma has carved out a niche market as a dermatology-focused company addressing the varied needs of a melting pot society.

Created in 1981, Galderma International is a Nestlé L'Oreal joint venture which has 33 wholly-owned subsidiaries worldwide and devotes 13.6% of revenue to research and development through its state-of-the-art facilities in France, Japan and the USA.

Passionate about dermatology, Galderma SA Managing Director, Jenny Wright joined the company four years ago after 18 years running the dermatology business unit for Roche. The company has doubled in size to 22 staff members, the majority women, since her arrival. During this prosperous time no new products have been launched but new ideas are in the pipeline.

"We are looking for products that answer the needs of our broader population. We have set up a Dermatological Ethnic Working Group in conjunction with the SA Dermatological Society to share information on ethnic skin types, facilitate skills transfer and assist with research through a specific study grant allocated to studying black skin types. There's a

huge knowledge gap with regard to black skin in general in the world and we hope to begin to address that. Here in SA we have the entire spectrum of skin types and thus the right opportunity for research," she said.

Galderma SA also sponsors the Dermatology Society's website which aims to educate South Africans about the possible dangers of product misuse.

"One of the major concerns in SA is the abuse of cortisone products," Wright says. "Many black people want to have lighter skin so they buy cheap bleaching creams from the 'grey' market and they are unaware these products can cause a rebound situation on the skin. The pigmentation can become blacker than before and cause irreversible other damage." Skin cancer is a growing problem for SA and although acne treatments account for around 60% of Galderma's business, there is a future pipeline including a therapy for non-melanoma skin cancers, photodynamic therapy.

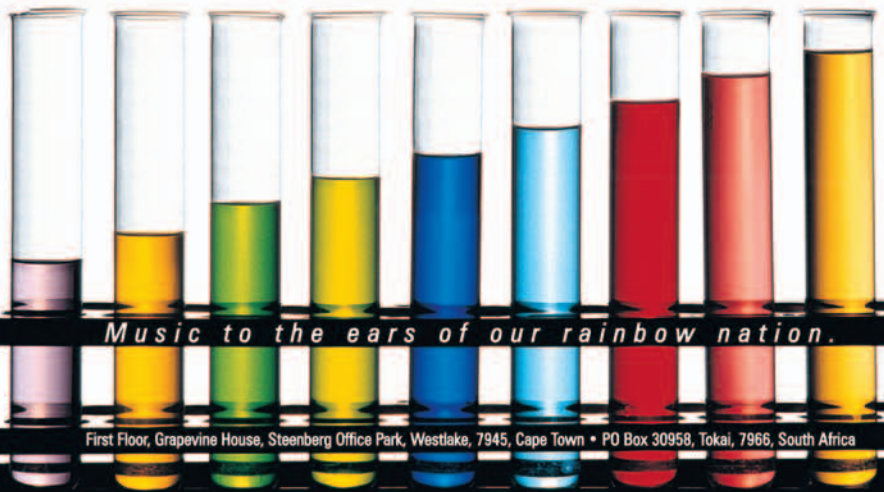
Wright said Galderma is dedicated to ensuring that South Africans have equal access to treatments on a global scale. "We will endeavour to make new innovative treatments overseas available to our own market and continue our efforts to educate the patients on all aspects of skin hazards and diseases."

SCALE OF BENEFITS

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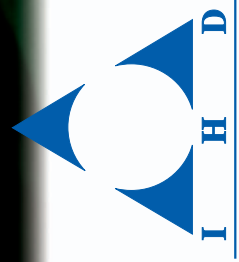
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Getting the Drugs where they are Needed

Recent years have seen radical changes in South Africa's healthcare distribution sector. Since the birth of direct distribution, pharmaceutical companies quickly learned that in this logistically challenging country fast and cost-efficient product delivery was not their forte. This evidently made way for distribution specialists to step into the lucrative market.

First off the mark in SA was International Healthcare Distributors (IHD), a finished goods logistics service provider that works with a number of multinational pharmaceutical manufacturers.

Chief Executive Officer of IHD, Graham Somerville, says the secret to direct distribution is never taking ownership of the goods.

The challenge of getting access to pharmaceuticals has long been problematic for the isolated South African population

"The product still belongs to the original manufacturers, and the direct chain comes from us directly into the market. There are no middlemen who add margins or bring costs into the system."

IHD has achieved significant milestones over a short lifespan, notably its success at significantly curtailing 'grey' or counterfeit products. Somerville says speed and cost-efficiency continues to be their main focus. "The ability to get products into the market quicker has been enhanced. The cost of distribution has significantly reduced by ten percent or more."

Somerville explains that the challenge of getting access to pharmaceuticals has long been problematic for the isolated South African population: "There are an enormous number of rural areas in the country and we have to make sure the products get there, and quickly." Maintaining a competitive pace is key in the distribution game. "We have a fundamentally different philosophy to the wholesaler. We don't make our margin in trading the products. We make it on the logistics of getting the product from point A to point B. If we don't do that, we don't get paid." Somerville concludes.

Keeping ahead of the game has also been the driving force behind Pharmaceutical Healthcare Distributors (PHD). During its five



Photo credit: IHD

Preparing orders

short years of existence PHD has grown from modest beginnings into an important industry competitor and national business. The company now operates out of a state-of-the-art warehouse that is not only one of the most impressive in the country but throughout the world.

Domestically, PHD is known as a pioneer in manufacturer-independent distribution services. In addition to its high-tech warehouse facilities, the company has developed a sophisticated online ordering service which is imperative in the time-sensitive pharmaceutical industry. With more than 60 percent of orders placed electronically, PHD has one of the most advanced web-based ordering portals in its field, and is therefore helping to ease the difficulties faced by a growing and logistically complex market.



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