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# The development of the South African biotech sector

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## Abstract

Like many other countries around the world South Africa is keen to develop its biotech capabilities. A vibrant biotech sector could have economic benefits and could also play a useful role in tackling diseases that predominantly affect South Africa but are currently underserved by the R&D efforts of multinational companies. However, South Africa's R&D infrastructure must be upgraded to meet the needs of the modern biotechnology sector, which relies on the latest advances in genetics and genomics. In 2001, recognising the challenges it faced in developing a mature biotech industry, the South African government published its National Biotech Strategy and allocated initial funding for a number of biotechnology regional innovation centres. There is also hope that South Africa's efforts to develop its biotech sector can serve as a useful example for developing countries around the world, but particularly for those within Africa.

## INTRODUCTION

Biotechnology is recognised as one of the key technologies that will shape medicine in the 21st century. A number of biotech medical products on the market have illustrated the potential of such treatments to modify diseases thus leading to better clinical outcomes.<sup>1</sup> Worldwide, there are now more than 350 biotech drug products and vaccines in clinical trials which are targeting more than 200 diseases, including various cancers, Alzheimer's disease, cardiovascular disease, diabetes, multiple sclerosis (MS), AIDS and arthritis.<sup>2</sup> Furthermore, biotechnology has resulted in a number of diagnostic tests being developed to detect medical conditions early enough to be successfully treated.

## BIOTECH ASPIRATIONS

Like many other countries around the world, South Africa is keen to develop its biotech capabilities. A vibrant biotech sector could have economic benefits and could also play a useful role in tackling diseases that predominantly affect South Africa but are currently underserved by the R&D efforts of multinational companies.

The emphasis on biotechnology is certainly influenced to a large degree by the outstanding success of the US biotech industry – an economic feat that most other countries would like to emulate. Currently there are estimated to be around 4,000 specialised biotech companies, but the most successful have been US in origin.<sup>3</sup> In 1992, revenues from the US biotech industry totalled US\$8bn but by 2003 this was closer to US\$40bn.<sup>2,3</sup> The US biotech industry is not only a major producer of medicines, but is also an important national employer. The US biotech industry employs around 200,000 people, thus making it a valuable contributor to the national economy.<sup>2,3</sup>

An interesting aspect of the US biotech sector is that it started off with limited finances and resources and yet even in the face of larger pharmaceutical companies it has managed to transform itself into a viable entity that represents an important source of new drugs. In fact many pharmaceutical companies are actively collaborating with smaller biotech companies. This is a mutually beneficial relationship as it provides the smaller company with the finance to continue its

**South Africa is already highly developed in areas such as medicine**

**South Africa has taken account of global biotech developments**

**For biotech companies to succeed, they must apply the latest advances in genetics and genomics**

R&D and for the bigger company it enables them to supplement their new drug pipeline with an innovative product. South Africa has taken note of such developments and believes that it has the means to build its own successful biotech sector.

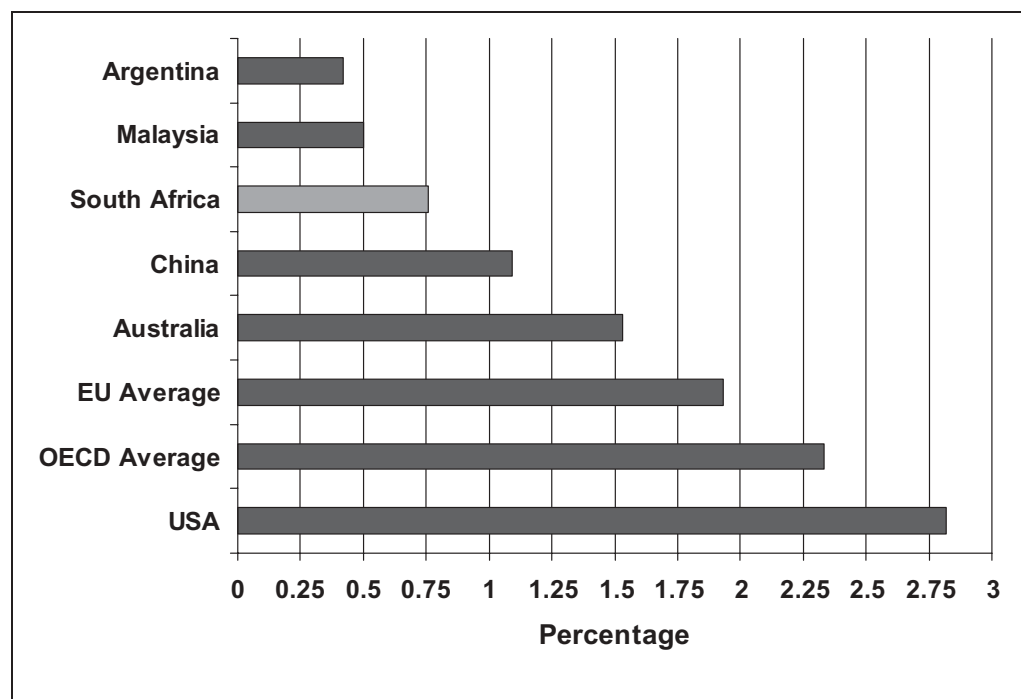
South Africa has also taken note of how the biotech sector is developing in other regions of the world, particularly in areas that face the same challenges in creating the right conditions for its growth. Countries that it has examined in this respect include Brazil, Cuba, Argentina, Thailand and China.<sup>4,5</sup> In order to harness any expertise it already possessed and develop those that it lacked, South Africa realised that it must set up a body to specifically promote biotechnology. This would specify the goals to be achieved and would be accountable for progress.

### ESTABLISHING A NATIONAL BIOTECH STRATEGY

During the apartheid regime, South Africa was isolated from the international community and was thus excluded from many developments in the technology field. As a result there was a considerable

effort to develop scientific expertise independently within the country to avoid reliance on external parties. The major areas that benefited from this approach were the arms, mining and textile industries.<sup>4</sup> South Africa was also already highly developed in certain areas such as medicine, being the location for the first human heart transplant in 1967.<sup>6</sup> In a sense there is an inherent ambition and overwhelming confidence within South Africa that they can overcome technological hurdles and challenge others around the world (Figure 1). The political landscape in South Africa has been completely transformed since the days of apartheid, but the elements that provided the in-house technology expertise during this time remain in place and are now being directed towards other fields such as biotechnology.

Although South Africa has an established reputation in the technological processes involved in brewing and agriculture, it has less experience in applying biotechnology to healthcare. For biotech companies to succeed they will need to apply the latest advances in genetics and genomics to their R&D. In 2001, recognising the challenges it faced



**Figure 1:** R&D as a percentage of gross domestic product  
Source: Dr Tai Schierenberg, Tech Forward

**Biotech will help South Africa develop a knowledge-based economy**

**In 2003 over 900 biotech and biotech-related projects were carried out in South Africa**

**A working relationship must be established between industry and academia**

in developing a mature biotech industry, the South African government published its National Biotech Strategy and allocated R400m over a three year period towards its implementation.<sup>5</sup> The country is also taking account of developments elsewhere in the world in order to create a realistic and long-term plan for its future industry.

There is a belief that the development of the biotech sector can help in achieving national goals in terms of reducing the impact of HIV/AIDS, and helping job creation, urban renewal, human resource development and regional integration.<sup>5</sup> It is particularly important for South Africa to develop a knowledge-based economy such as biotech because traditional industries such as mining, primary agriculture and manufacturing can no longer be solely relied upon to drive economic growth in the country.

## CHALLENGES

One of the initial tasks was to examine the prevailing set up for biotech R&D in South Africa and identify both weaknesses and strengths. A 2003 survey revealed over 900 biotech and biotech-related research projects being carried out in South Africa, indicating the presence of a strong research base.<sup>7</sup> However, despite this large number, very few products from these projects have been commercialised and this was largely put down to the unfocused approach to national biotech R&D. Although South Africa's National System of Innovation (NSI) had served it well in the past, it was no longer ideally structured to cope with the demands of biotech innovation in an era dominated by advances in genetics. In particular the system in operation suffered because of the poor cooperation between institutions developing biotech approaches and those using the technology within industry and government.<sup>5</sup> It was found that many groups in South Africa were involved in new areas of biotech research, but that their findings were rarely taken beyond academic circles. Furthermore these

groups were found to lack the critical mass necessary to compete internationally and were also underfinanced.<sup>5</sup> As such it was felt that important opportunities had been missed to exploit the existing technological base, and that it needed reform.

Local observers have called for more active engagement between academic bodies and industries in the field of biotech and believe that the mining sector serves as a useful example in this regard.<sup>8</sup> The mining sector has been proactive in providing finances for engineering faculties in universities. This process has fostered a collaborative spirit and led to the training of suitably qualified graduates for the industry.<sup>8</sup> One of the approaches used to encourage and facilitate university-industry collaborations is the establishment and development of Technology Transfer Offices that are equipped with the expertise to forge and negotiate these relationships. The government's Technology and Human Resources for Industry Programme (THRIP) funding initiative has also been an important source of funding for university research groups, matching industry financial contribution for joint projects up to a 1:1 matching basis.<sup>8</sup> This type of initiative benefits both sets of parties financially, by allowing institutions to purchase equipment and provide bursaries to students, while allowing biotech companies to gain from the research output and expertise.<sup>8</sup>

Equally important is that it establishes a working relationship between industry and academia. After all, upon completion of their studies, graduates will be seeking employment and so local industry can benefit from the already existing relationship with universities. For example, PlatCo Technologies, which is a subsidiary of Shimoda Biotech, has an ongoing partnership with the University of Port Elizabeth to develop novel and improved platinum-based anti-cancer compounds.<sup>8,9</sup> Shimoda is also developing a new formulation of propofol, which is a well-known anaesthetic product.<sup>9</sup> The

company is hoping to seek investigational new drug (IND) status for the drug from the US Food and Drug Administration (FDA) next year.<sup>9</sup> Its arrangement with the University of Port Elizabeth is thus an important part of its ability to control costs as well as representing a source of additional skills. Shimoda has been fortunate in securing private funding through financial services group Peregrine, the Industrial Development Corporation, Cape Biotech and local venture capital fund Bioventures.<sup>9</sup>

Recognising these weaknesses, a key part of the new national strategy has been to create a number of biotechnology regional innovation centres (BRICs) in order to implement the National Biotech Strategy on both a regional and national scale by acting as focal points for the development of biotechnology platforms.<sup>5,10,11</sup> The three BRICS that have been established are BioPAD (Biotechnology Partnerships and Development), Cape Biotech and LIFElab East Coast Biotechnology Consortium (Table 1).

The primary role of the BRICs is to implement the strategy by investing the allocated R400m funding in start-up biotech companies and developing human capacity to support the growing industry through various capacity development programmes. The BRIC activities will be overseen by the Biotechnology Advisory

Committee (BAC), which will ensure development of the sector on a national level through the coordination and integration of the regional activities. Furthermore, by training local scientists in the field of biotechnology, South Africa will have a resource base to staff the industry as it develops in the future.<sup>11</sup> There is a worry that unless the general environment for biotech improves, life science graduates may seek alternative careers, thus stifling growth of the sector.<sup>5</sup> In particular, there is concern that those trained in biotechnology disciplines may opt for a career abroad. For example, the average South African postdoctoral bursary is 40 per cent of that abroad.<sup>5</sup> The companies and technology platforms that have received BRIC funding to date are listed in Tables 2–4.

Although there is much to gain economically through the establishment of a biotech industry, South Africa is also keen for the industry to help develop treatments for diseases that have a heavy regional impact such as HIV/AIDS, malaria and tuberculosis.

## FUNDING AND RESOURCING ISSUES

Guaranteeing adequate funding on a long-term basis has been a challenge for emerging biotech sectors around the world.<sup>1</sup> Even in the USA, where funding conditions are much better, many biotech

**Biotech Regional Innovation Centres (BRICs) have been created**

**South Africa hopes to use biotech to tackle HIV/AIDS, malaria and tuberculosis**

**The BRICs will invest R400m in biotech**

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

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

**Table 2:** Projects being supported by BioPAD

Project focus	Details
BioPAD Seed Capital Alliance Platform For Enterprises (Bioscape) Vaccines and Enhanced Therapeutics Platform for Animals (VETPLAN) Bioresource Centres Platform (BioCEP) Microbial Technology Platform (MiTEP)	Bioscape is an alliance made of BioPAD and investors to support regional biotech initiatives with early stage venture capital. VETPLAN aims to produce vaccines that focus on diseases posing a risk to animal and human health. BioCEP will support regional centres that preserve and distribute biological materials and information to biotech researchers. MiTEP focuses on microbial and enzyme systems of relevance to mining, environmental, animal feed and industrial biotechnology research.

**Table 3:** Projects being supported by the Cape Biotech

Project focus	Details
Capar (Cape Microarray Facility)	Capar is a technology platform established in January 2004 and situated at the University of Cape Town. It provides an affordable DNA microarray service to life science researchers in South Africa.
Biovac (Vaccine platform)	The Biovac Institute aims to develop a high-quality biotech manufacturing facility to produce clinical trial doses of developmental biotechnology. A rabies project is currently being funded to produce a low-cost, high-yield and high-quality vaccine.
Shimoda Biotech	Shimoda Biotech focuses on the development of proprietary drug delivery systems.
Synexa Life Sciences	Established in 2001, Synexa manufactures high-value, difficult to produce, microbial secondary metabolites for the life science and pharmaceutical industries.
Genecare Molecular Genetics	Genecare is a genetic testing company that aims to commercialise rapid and standardised genetic testing systems, with an emphasis on the detection of disease-related mutations.
NCSA	National Carotenoids South Africa will produce a variety of carotenoids through algal cultivation and extraction.
Disa Vascular	Disa Vascular, a medical device company that is currently testing their developed drug eluting stent, which will help prevent restenosis in cardiac patients.
SunBio	SunBio focuses on developing commercial yeast strains with enhanced nutritional benefits.

**Table 4:** Focus areas of LIFElab

Project focus	Details
Infectious Diseases Programme	The infectious diseases programme focuses on three diseases (HIV/AIDS, tuberculosis and malaria) that account for the greatest healthcare burden of South Africa. Between 60 and 75 per cent of projects will be dedicated to developing therapeutics and preventative products for these diseases.
Bioprocessing	The aim is to develop a bioprocessing project pipeline that maximises the East Coast region's competitive advantage in liquid fermentation technology.
Technology platforms	Platforms will be funded based on the regional needs of LIFElab's stakeholders. There is considerable interest in functional genomics.

**Biotech drug development is risk-intense**

**Companies require adequate funding to pursue R&D**

companies have failed. The problem is that although biotech can be hugely profitable in the long term, there are considerable risks involved in developing drugs. A considerable financial investment is required at the beginning of the R&D process, without there being any guarantee of future success. It is estimated

that drug development costs on average around US\$897m and that only about 15 per cent of new drugs entering development subsequently reach the market.<sup>12,13</sup> If companies are to be persuaded to take on these drug development risks then they must be assured of funding.<sup>1</sup>

**More R&D must be directed towards 'neglected diseases'**

In South Africa five potential areas for financing the biotech sector were identified by the government:<sup>5</sup>

- Government Department Grants to Science Councils;
- specific competitive and innovation funds;
- Department of Education funding of the higher education sector;
- private sector, local and international;
- international donors and funding agencies.

**In 2001, 68 venture capital firms were identified in South Africa**

Private capital is likely to be limited initially, therefore having dedicated government funding is vital in order to kick start the biotech sector in South Africa. In 2001, the government identified around 68 venture capital firms in the country, which controlled R28bn, but few were found to be enthusiastic about funding the emerging biotech sector.<sup>5</sup> This can be attributed to a lack of understanding of both the industry and risks involved. In order to encourage greater involvement, a national conference, Bio2Biz 2004, was launched to address commercialisation issues unique to this industry and to provide private investors the opportunity learn about the industry and to meet with potential projects.

**The healthcare situation in developing countries is complex**

**TAILORING BIOTECH R&D FOR UNMET MEDICAL NEEDS**

One of the biggest challenges for governments and industry in the future is to decrease the health disparities between poor and affluent populations and to improve access to medicines across the world. Unfortunately, the current R&D focus of the international pharmaceutical industry is not overtly aligned with the areas of unmet medical need in developing countries and this has led to considerable public controversy. As the

purchasing power of the populations in these areas is low, there has been little commercial incentive to invest in R&D for diseases predominantly affecting poorer nations. This has led to use of the term 'neglected diseases' to refer to these areas of unmet medical need.

Furthermore, the pharmaceutical industry has been heavily criticised for its pricing policies. Médecins Sans Frontières (MSF) has stated that one-third of the world's population lack access to essential medicines and that prices are too expensive for such products if they are available in developing countries.<sup>13</sup>

In June 2005, MSF, other non-governmental organisations, scientists and a number of Nobel laureates launched a global appeal to significantly boost research for neglected diseases.<sup>14</sup> The terminology covers a wide range of disorders, such as malaria and tuberculosis. Although US\$100bn is spent annually on health research globally, MSF believe that only US\$3bn would be needed to significantly improve the outlook for neglected diseases.<sup>15</sup> According to MSF, the profit-driven and intellectual property approach of the pharmaceutical industry has skewed research priorities. In their defence, pharmaceutical companies state that the healthcare situation in developing countries is complex, and that issues such as the general healthcare infrastructure, establishment of efficient drug distribution systems and training for healthcare personnel must be tackled alongside the development of new treatments.

On a global basis, the laws relating to pharmaceutical patents are in principle regulated by the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>16</sup> The philosophy behind the TRIPS agreement was to ensure that the manner in which intellectual property is protected also serves social goals, but the agreement has been put to the test by the ongoing global HIV crisis.<sup>17</sup> In particular, the South African government has been vocal in its

**Compulsory licensing can be used in emergency health situations**

**HIV subtype C accounts for over 90 per cent of infections in Southern Africa**

**South Africa has the largest economy in Africa**

criticism of the pharmaceutical industry's pricing of anti-retroviral drugs. In 1997, South Africa decided to set aside international guidelines on intellectual property, stating that the enormity of the AIDS crisis gave it 'medical emergency status'. Under TRIPS Article 31, countries may use compulsory licensing for domestic pharmaceutical supplies during health emergencies.<sup>17</sup> This led to a legal battle with the pharmaceutical industry, with subsequent considerable adverse publicity for the companies involved. Following a statement by the government that its legislation would be implemented in a TRIPS-compliant fashion, the action by the pharmaceutical companies was withdrawn.<sup>17</sup>

One of the specified aims in the South African National Biotech Strategy is therefore to direct some of the domestic biotech R&D effort towards areas of unmet medical need. This would allow it to become less dependent on outside research efforts. All BRICS are being encouraged to invest in relevant projects (Tables 2–4), and it is hoped that they will eventually attract foreign interest in their work. For example, there has been foreign interest in the bioinformatics approaches being used by South African research groups for areas such as AIDS, dengue fever, tuberculosis and other tropical diseases.<sup>18</sup> In 2002, the South African National Bioinformatics Institute

hosted a training course sponsored by the World Health Organization that examined bioinformatics approaches to neglected diseases.<sup>18</sup>

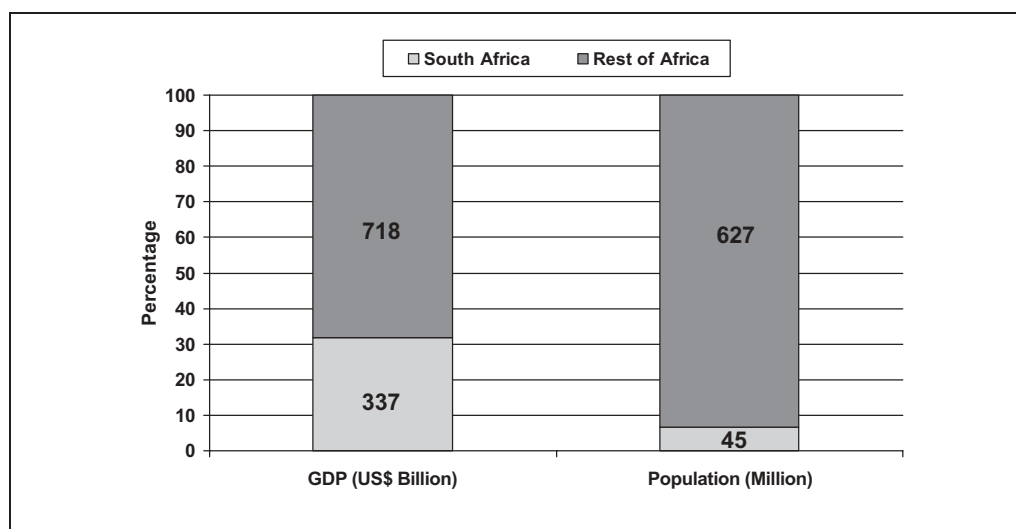
The South African AIDS Vaccine Initiative (SAAVI) was established in 1999 to coordinate the research, development and testing of HIV/AIDS vaccines in South Africa. SAAVI works with a range of national and international partners, but focuses primarily on the development of subtype C HIV/AIDS vaccines (as HIV subtype C accounts for over 90 per cent of infections in the southern African region).<sup>19</sup> SAAVI's expertise will be important for testing vaccines developed by the BRICs.

### CONCLUSION

South Africa's efforts to develop its biotech sector can serve as a useful example for developing countries around the world, but particularly for those within Africa.<sup>20</sup> Africa could benefit enormously from biotech advances, both from an economic standpoint and in terms of health improvements for the local populations. At present, South Africa has the largest economy in Africa, accounting for over 30 per cent of the continent's GDP (Figure 2) and so in many ways it is best placed to pioneer the uptake of biotech technology within the continent. In July 2005, the African Union announced that it was setting up a

**Figure 2:** South Africa in relation to the rest of Africa

Source: Dr Tai Schierenberg, Tech Forward



### The South African biotech sector is an emerging force

biotechnology advisory panel.<sup>21</sup> In the biomedical field, the panel hopes to draw upon the expertise of South Africa's emerging biotech sector.<sup>21</sup>

At present, the R&D efforts of major international companies are not seen publicly as placing a high enough priority on the diseases that predominantly affect Africa. Thus many observers believe that the South African biotech sector represents the way forward. If local biotech companies are able to overcome the technological and financial hurdles of biotech drug development, they will already have the necessary incentive to tackle local diseases as they affect communities that they more closely identify with. In October 2005, South Africa hosted a bio and medical technologies conference called Lifesparks 2005. The event was primarily funded by the Innovation Fund, a government initiative, to promote the biotech sector and enable prospective entrepreneurs to meet with potential business partners.<sup>22</sup> The Innovation Fund will also be showcasing 30 of its biotechnology projects.<sup>22</sup> Events such as these will be important to demonstrate to an international audience that the emerging South African biotech sector is innovative and represents a potential source of new medicines.

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