



The Impact of the National Biotechnology Strategy on the South African Biopharma Industry

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Context I

- **The National Biotechnology Strategy published in 2001**
- **Process followed for drafting it:**
 - **A group of experts**
 - **Wider consultation with stakeholders**
 - **Adoption and publication**
- **Call for Expressions of Interest for the establishment of BRICs**
- **Selection of three regions for setting up the BRICs (early 2002)**
- **Establishment of the three BRICs:**
 - **Cape Biotech in the Western Cape**
 - **BioPAD in Gauteng**
 - **ECOBIO/LIFElab in KZN**
- **In addition national instruments were established:**
 - **PUB**
 - **National Bioinformatics Network (NBN)**
 - **PlantBio**

Context II

- **The mandate for the BRICs was to focus on:**
 - Commercialising biotechnology innovations coming out of universities, research councils, private sector
 - Three focus areas of human health, bioprocessing, animal health
 - Plant biotechnology for PlantBio
 - Establish a national bioinformatics capacity to serve the biotechnology innovation needs (NBN)
 - Build research-industry linkages
- **Emphasis was near market support:**
 - Assumption was that there would be enough projects in the near market stage
- **Evolving and confusing definitions around a number of key mandates**

Setting the Parameters

- **Funding:**
 - **Key assumption was that this was solely for innovation and excluded basic research**
 - **Indirect adoption of a linear model of innovation and product development**
 - **Silo / Bubble i.e. funding strategy was in isolation with no link to early stage (basic research) or late stage (into the market)**
- **Some of the challenges were:**
 - **A lack of clear policy leadership**
 - **A lack of common definitions for innovation and biotechnology**
 - **Misalignment of expectations between the key stakeholders viz. practitioners, funding managers and funder**
- **Focus areas – too broad and lacked strategic coherence**
- **Projects and Portfolio sizes and mix**

Strategic Intent

- The Strategic Intent for the human health side was to leverage the funding to develop products in:
 - Diagnostics
 - Pharmaceuticals
 - Preventatives
 - Neutraceuticals
- By and large the focus was to target the disease burden in South Africa – infectious diseases of HIV/AIDS, TB and malaria
- Creation of technology platforms in a few niche areas
- Industry linkages and creation of biotechnology start ups

Note: To date over half a billion rands has been spent!

Pharmaceutical Market

- No South African innovated product in the top 20 by either rand value or sales volume
- Leading product : Stocrin
- A few key products (including statins, some biologics) will come off-patent within 5 years (high value)
- Anti-HIV drugs will soon become # 1 as a class by volume
 - Biggest client for this class is government
- No South African innovators in the top tier
 - A worthy mention is NBI in the fast growing market segment

Some Key Facts






- Total sales were over R15,5 billion in 2007
- Aspen and Adcock Ingram were ranked in the Top 3
- Enaleni was also ranked in the Top 10 by sales
- Stocrin was ranked # 1, followed Lipitor
- Only one other anti-HIV drug was in the Top 10 – Aspen Lamivudine
- Generics contributed just under 20% of product sales by Rand value, and 25% by volumes
- Non-generics contributed a staggering 48% of sales by Rand value

Contribution of the NBS

- **Not likely to happen within the next 5 years**
- **Re-alignment of expectations**
 - **Payback is usually in excess of 10 years for both public and private investment**
- **Best shot will be those projects that are licensing and enhancing third party technologies**
- **Diagnostics will most likely provide the first wins, provided government procurement support is secured**
- **Key Success Factors:**
 - **Mid-tier local manufacturing champions (technology in-sourcing)**
 - **Leveraged funding (tax breaks, req. ops company with cash flows)**

International Benchmarking

India

-  Developed an indigenous capacity via the generics route
-  Medicinal chemistry capacity well developed, and used it as a lever to advance to innovation
-  IPR dimension (supportive)
-  Local market
-  Biocon Case

Brazil

-  Largely similar to India including IPR issues, protected markets

Cuba

-  Strong central planning and coordination with key health mandates
-  Western Poll
-  Massive training and development programmes

Some Key Lessons

- 🌐 **Move from a ‘low technology’ base – allowing for building up of competencies**
 - 🌐 **India & Biocon at company level**
- 🌐 **A leveraged market in the form of a hybrid AMC is critical in securing future sustainability**
 - 🌐 **Start with the market (as opposed to technology push)**
 - 🌐 **Potential for government support of the establishment of manufacturing capacity**
- 🌐 **Aggressive focus on skills development (Cuba)**
- 🌐 **Initially focus on process and manufacturing technologies**

What Needs to be Done?

- **Move away from the dominance of practitioners as drivers of Strategy Development**
- **Negotiate with the market up-front i.e. during formulation of new strategic outputs**
 - **Find homes for the technologies or dump them**
- **Move away from the DST-centric (innovation/technology push) to a more DTI/DoH (market makers) inclusive approach in project development**
- **Provide policy leadership, especially operational parameters including common definitions and contextual frameworks**
- **Focus should be on very narrow, niche areas defined by the market – so we can build real critical mass**
 - **These must be funded aggressively**

Strategic Options

- Review the current Human Health Portfolio in BRICs
 - Consolidate the IP Assets into a few companies with critical mass
 - This may also be done through the auspices of TIA (Brazil approach)
- Utilise data from the National Biotech Audit and IMS (and other credible sources) to identify market gaps in the national and continental markets
- Leverage the potential synergies between the Industrial Strategy and the 10 Year Innovation Strategy
 - These must form the basis for any review of the Biotech Strategy
- Focus on what can be done in the first instance:
 - Generics play
 - Artificial markets through DoH procurement
- Is there a role for a State-owned Pharmaceutical manufacturer?

A Ray of Sunshine

- 🌐 Collaborative projects like iThemba and Arvir provide a potential model for going forward with their focus on process technologies
- 🌐 Some platforms like functional genomics can contribute to addressing immediate market needs in diagnostics like HIV (resistance and viral loads), MDR and XDR TB
- 🌐 CSIR capacity can be enhanced and re-directed to address some of the manufacturing issues
- 🌐 State-owned entities like NBI and BioVAC provide platforms for a ramped up state investment in capacity