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 bilion 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