Perspectives from a new entrant in Biopharmaceuticals
The 6th CSIR Conference – Ideas that work for Industrial Development

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Africa’s Pharma market is poised for growth

Market forecast, $ billion

Sales per capita, $

2010 2020, base 2020, realistic 2020, optimistic

14.5 37.6 45.1 58.7

17.5 44.1 52.2 66.5

14.4% 11.7% 9.8%

CAGR¹

³ Compounded annual growth rate.

Source: African Development Bank; BMI Research; International Monetary Fund; World Bank; World Health Organization; McKinsey analysis

McKinsey & Company
Global Healthcare is Big Business!

Global health care spend projected to reach $8.7 trillion by 2020.

% of GDP spent on health care should also rise slightly, from an estimated 10.4 % in 2015 to 10.5 % in 2020.

Where is the growth expected?
Emerging and lower-income countries will drive the rise in health care expenditures through 2020 as well as the expansion of services in developed countries.

South Africa has an attractive epidemiological profile for Biopharma.

- South Africa’s evolving epidemiological and demographic profile presents opportunities for Biopharma Companies.

DALYs Lost To Communicable And Non-Communicable Diseases In South Africa

f = forecast. DALYs = disability adjusted life years. Source: BMI’s Disease Database.
There is Rush for new Medical innovations

AstraZeneca to acquire MedImmune

AstraZeneca agreed to acquire MedImmune for $58 per share, or about $15.2 billion. Including net cash of about $340 million, the purchase price is approximately $15.6 billion, the drugmaker added. Jon Symonds, the company's chief financial officer, noted that the bidding for MedImmune was "ferociously competitive" and the drugmaker is taking on debt for the first time with this acquisition. AstraZeneca's shares fell as much as 5 percent on Monday.

AstraZeneca to acquire Pearl Therapeutics to strengthen respiratory portfolio

Pfizer to buy Wyeth for $68 billion

Pfizer to buy Medivation for $14 Billion

Bayer to Buy Cancer-Drug Partner Algeta for $2.9 Billion

Bayer AG agreed to buy Algeta ASA, its partner on the prostate-cancer medicine Xadago, for about $26 billion kronor ($2.9 billion) to gain control of the drug and experimental radiation therapies.
Role Players in the bioeconomy: SA Presepective

Figure 8: South African Vaccines and Biologicals Value Chain Players

Enabling Environment for SA Bio-Entrepreneurs

Investor Friendly Environment
Institutional Infrastructure, IP Rights, Technology Infrastructure, SEZs

Investment in Human Capital
Increased investment in Science & Technology Research (NRF)

Regional Integration
New collaborative partnerships, Regulatory Harmonization, Trade-Blocks, Research Collaboration, Resource Sharing etc.

Robust Intellectual Property Laws
Protection of the Inventors/Innovators, Public Institutions, Private Investors.

Local Investment in Early stage research
DSTs continued investment in early stage research where risk is highest

Increased Focus on NCD
Non Communicable Disease on the Rise and now attract a significant share of Health Budget

Growing Middle Class
Affordability is on the rise with growing middle class with more disposable income

Power of Genomics & Big Data
Bioinformatics tools have become more powerful & widely available

Growing Middle Class
Affordability is on the rise with growing middle class with more disposable income
Challenges & Opportunities

**Challenges**

- Regulatory hurdles for Ready-to-Market-products and technologies
  - MCC backlogs – Local
  - Lack of mutual recognition (EU, US, etc) – e.g. Medicinal status of CAMs
- Underdeveloped Biotech VC environment
  - Local VC players do not rush to invest in early stage Biotech ventures
- Continuity challenges within Research Institutions
  - Scarce talent pool, high staff turnover negatively impact continuity

**Opportunities**

- Exciting IP and technology stock at various research institutions (CSIR, HEI, NECSA, etc)
- Many markets/countries are open for business for SA Biopharma
  - Faster registration lead times in SSA
- International Tech VC appreciate and recognize SA as an Innovative nation
- SA Govt Tax incentives encourage early stage high risk investment
- Convergence of technology platforms and capabilities reduce resource requirements for new entrants
Priority Medicines for Europe and the World
Update Report, 2013

Gap 1: Treatment(s) exist but will soon become ineffective;
• Antibacterial resistance, Pandemic influenza

Gap 2: Treatment(s) exist but the pharmaceutical delivery mechanism or formulation is not appropriate for the target population;
• Cardiovascular disease, HIV/AIDS, Cancer, Depression, Diabetes, Pneumonia, diarrhoeal diseases and neonatal diseases and conditions; Malaria, TB, Neglected tropical diseases,
• Postpartum haemorrhage and maternal mortality

Gap 3: Treatment does not exist OR is not sufficiently effective.
• Acute stroke, Osteoarthritis, Alzheimer disease and other dementias, Chronic obstructive pulmonary disease, Hearing loss, Low back pain, Rare (including orphan) diseases

Gap 4: Global risk factors with no or insufficient pharmaceutical treatment
• Tobacco use cessation, Obesity, Alcohol-related diseases

http://www.who.int/medicines/areas/priority_medicines/Ch9_Conclusions.pdf?ua=1
BGM’s Key focus areas

**Therapeutics**
- Small molecules: Specialty Generics
- Large Molecules
  - Biosimilars: Plant based expression systems
  - IV to ORAL Reformulation: INSULIN
  - IV to ORAL: GNRH analogues
  - Radiouclide Therapeutics
  - Medications derived from Herbal Extracts

**Theranostics**
- Radionuclide + MAB Conjugates
- Radionuclides + Aptamers
- Radionuclides + TKIs

**Diagnostics**
- TC-99 Cold Kits (ECDG) for Cancer Imaging
- HANKS TB Diagnostic: Platform Test
R600m deal to develop theranostics cancer treatment

14 MAR 2017 |  

A breakthrough in cancer diagnosis and treatment, and the subsequent R600m deal to take it to market, proves not only that drug research and development is alive and well in South Africa, but that collaboration between the government and the private sector is not only possible, but can deliver positive results.

As the second leading cause of death globally, cancer was responsible for 8.8 million deaths in 2015, approximately 70% of which occurred in low- and middle-income countries. The global burden of cancer will grow over the next two decades, with an estimated 22 million new cases and 13 million deaths each year by 2030.

The University of Cape Town (UCT) has entered into a landmark partnership with BGM Pharma and the South African Nuclear Energy Corporation (NECSA) to bring a new theranostic called GluCAD to market. The term “theranostics” was coined to define an agent used for diagnosis via imaging followed by therapy, and it’s fast becoming the norm in personalised medicine.

A first for South Africa, the partnership signifies a breakthrough in cancer diagnosis and treatment. In collaboration with a team at NECSA, Professorrop Parker (Institute of Infectious Diseases and Molecular Medicine), Professor Roger Hunter (Department of Chemistry) and their PhD student Cathryn Driver, developed a molecule for next-generation chemotherapy.
Promoting innovation & Industrialisation

*Practical Considerations*

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<th>Strategic Issues</th>
<th>Focus</th>
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<td><strong>Public-private partnerships</strong></td>
<td>• <strong>PPPs and PDPs</strong>, both in a developed and developing country setting. Especially lessons from initiatives such as IMI and TI Pharma. Local examples such as BGM-NECSA/CSIR/HEI, SA Vaccines development &amp; Manufacturing, etc.</td>
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<td>• <strong>Creation of a Biopharma manufacturing Cluster</strong> – Local innovations need local manufacturing base</td>
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<td><strong>Stimulating innovation through redesigning the regulatory system</strong></td>
<td>• <strong>Possibility for regulatory innovation</strong>, including e.g. measures on orphan drugs/pediatrics. Include points on prevention within the regulatory framework.</td>
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<td><strong>Pricing and reimbursement to advance innovation</strong></td>
<td>• The <strong>integration of priorities with pricing and reimbursement</strong> (P&amp;R) procedures. Incentives that can be used to stimulate innovation.</td>
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<td>• <strong>Real-life data and learning from practice to advance innovation</strong></td>
<td>• <strong>Using observational and real-life data</strong> as an input for priority setting and stimulating innovation.</td>
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<td><strong>Models for stakeholder involvement, including patients and citizens</strong></td>
<td>• Focus on how patients and citizens can be involved in decision making around pharmaceutical innovation/priority setting.</td>
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