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Reform for Investment & Sustainable Economies

Africa RISE

Botswana Pharmaceutical Sector Study

"Reform for Investment and Sustainable Economies"

A programme of technical assistance for Eastern Africa, Southern Africa and the Indian Ocean

Africa RISE reports



Market Assessment Report

Sector Study Report

- To identify key pharmaceutical market attributes, including size, structure, growth potential, and trends
- To identify local pharmaceutical needs, industry capacity, challenges
- To identify investment opportunities based on market data

- To identify gaps in the Pharmaceutical regulation, industrial policy, manufacturing management, skills gap, manufacturing capacity challenges
- To map Botswana's pharmaceutical ecosystem
- To suggest a model and way forward for the pharmaceutical sector of Botswana
- To identify investment opportunities



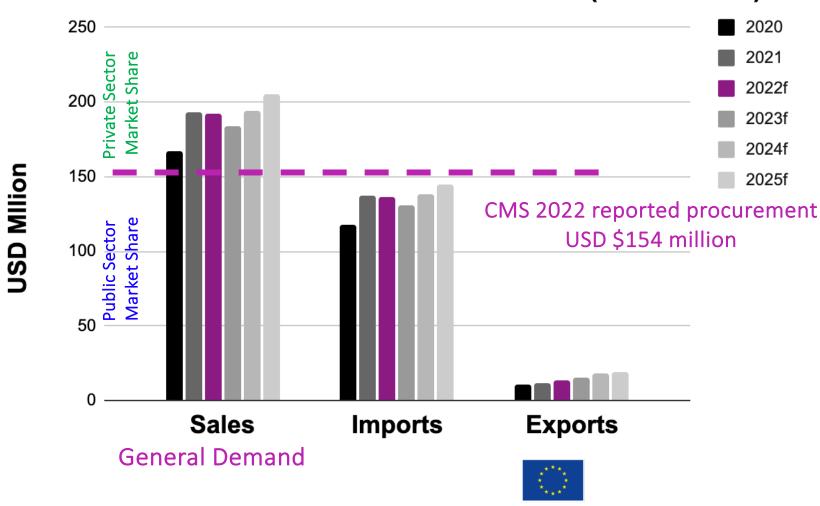
Pharmaceutical market assessment

Size of Botswana's Pharmaceutical Market



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Bostwana Pharmaceutical Trade Forecast (USD million)



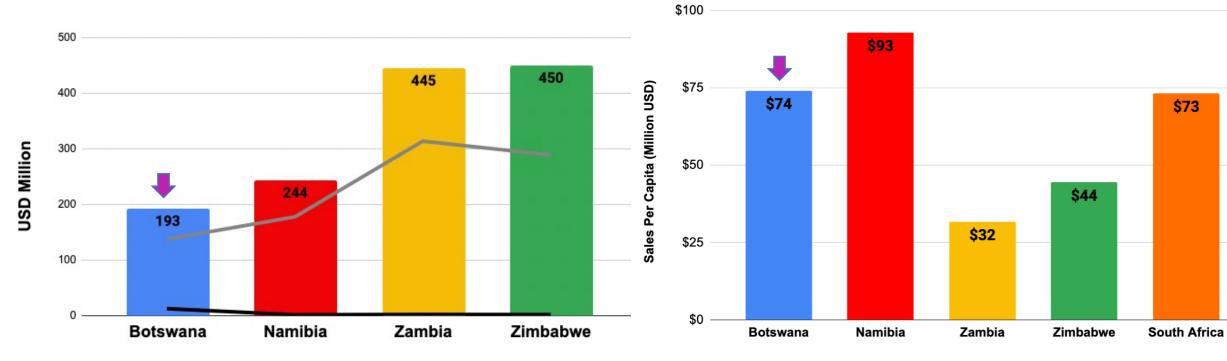
According to Fitch Solutions Report:

- Estimated size in 2022: USD \$193 million.
- Estimated Forecast 2025: USD \$205 million.

ZAZIBONA* Regional Size of Pharmaceutical Market



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ZAZIBONA Pharmaceutical Trade 2021

Pharmaceutical Sales Per Capita (Million USD) vs Country

According to Fitch Solutions Report:

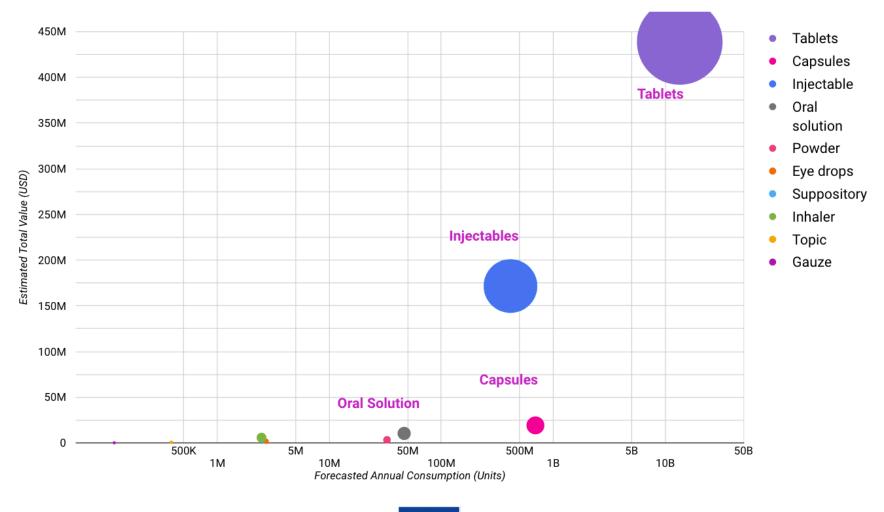
- Estimated size in 2022: USD \$1.3 Billion.
- ***ZAZIBONA:** Botswana, Namibia, Zambia, Zimbabwe

• Bostwana has the second pharmaceutical sales per capita of the region.

Conventional Medicines: 3 countries: Dosage Forms



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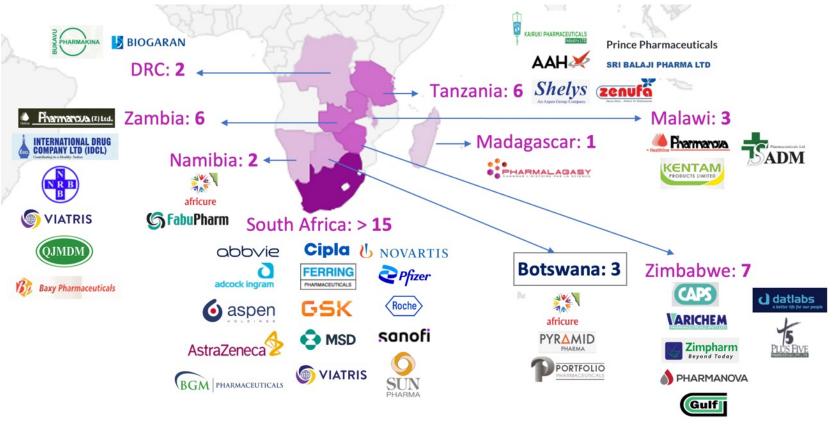


Pharmaceutical manufacturers in SADC Region



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Botswana is not the only country in the Sub-Saharan region trying to develop a pharmaceutical industry



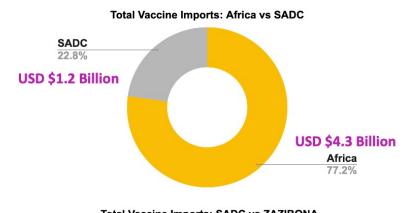
Recommendations:

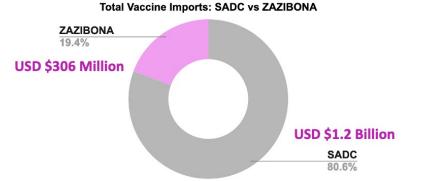
- Market Segmentation
- Promotion of collaboration among manufactures

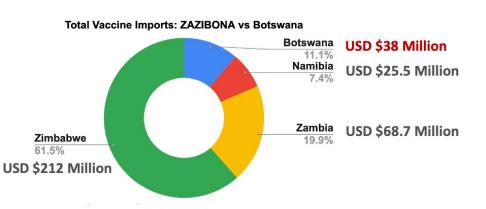
Requirements: BoMRA-- WHO ML3

Biopharmaceutical Products: Vaccines

Vaccines Market Size









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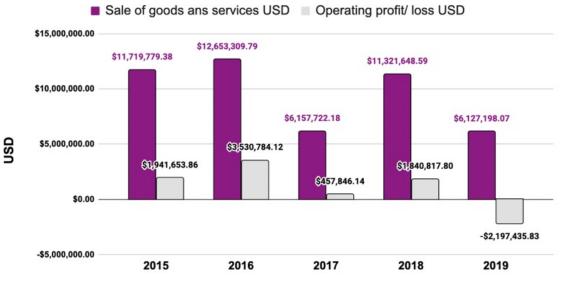
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- Manufactures 6 types of veterinary vaccines
- Exports up to 30 different countries.
- Only pharmaceutical manufacturer in Botswana that follows the complete value chain.
 Botswana Differentiator

BVI Sales of Goods and Services vs Operating Profit Loss in USD 2015-2019

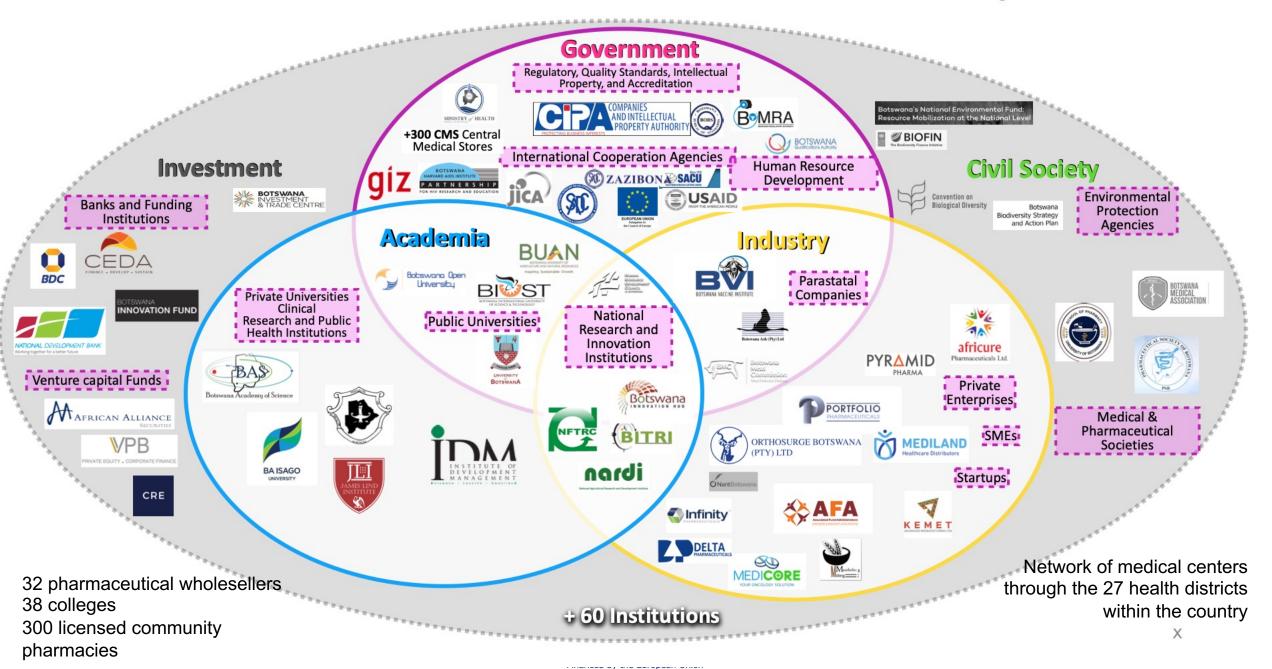


Requires investment to broaden their veterinary vaccines portfolio and start developing vaccines for human use.

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Botswana's Pharmaceutical Sector and Innovation Ecosystem

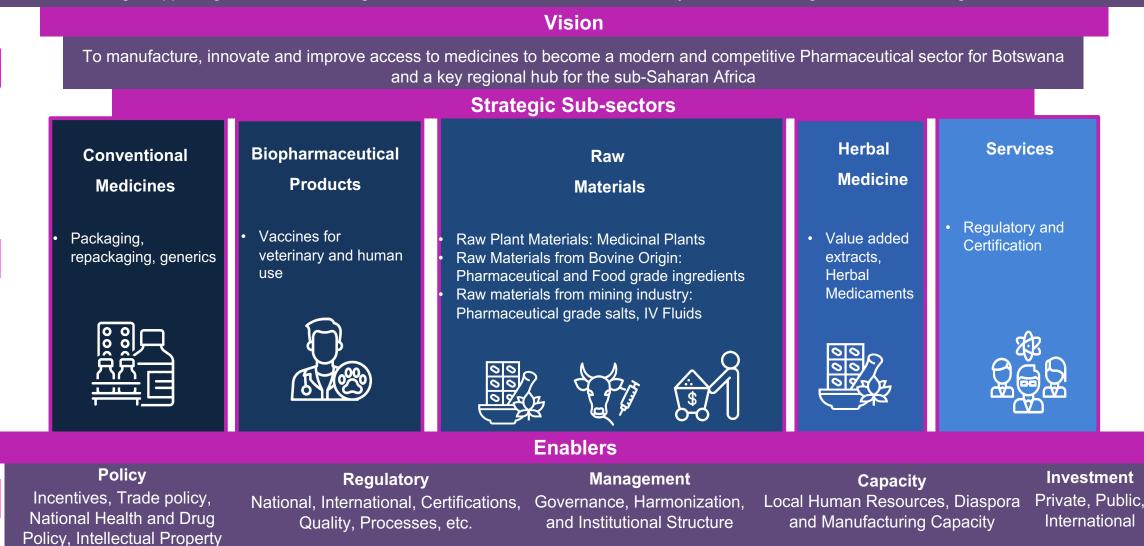


A model for Botswana's Pharmaceutical Sector

Botswana's Pharmaceutical Sector

Mission

To develop the pharmaceutical sector of Botswana and diversify its national economy through facilitating access to medicines, creating higher value products and services through supporting local manufacturing, traditional medicine, and innovation ecosystem and creating a safe and enabling framework for investors



3

4

protection policies

Investment opportunities to detonate the development of 5 strategic subsectors

1. Conventional medicines



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- The development of the conventional medicines industry in Botswana presents an opportunity for specific product categories as antiretrovirals, analgesics, cardiovascular medicines, and anti-infectives.
- There is a demand forecast of over 13 billion units of tablets with an estimated value of over USD \$400 million for Botswana, Zimbabwe and Zambia.





2. Biopharmaceutical Products





- The expansion of veterinary vaccine production and the manufacturing of human vaccines presents a significant opportunity in Botswana's biopharmaceutical industry.
- BVI is currently producing six different vaccines and exports for a value of around USD \$7.5 million.



3. Raw materials



- Unlike pharmaceutical manufacturers, no manufacturer of pharmaceutical grade raw material currently exists in Botswana.
- Based on the pharmaceutical ecosystem of Botswana researched so far, there could be
 potential for initiating an industry in the medium- or long-term in Botswana considering
 synergies with the existing industry in the country.



Raw materials from bovine origin



Raw plant materials



Raw materials from mining industry



4. Herbal medicine



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- In Botswana 47 plant species belonging to 45 genera and 29 families are used to treat various diseases and health conditions.
- Despite its accessibility, affordability, and effectiveness, there is a lack of investment and limited scientific research in this field in Africa





5. Services

- Services in regulatory, certifications and training play a crucial role in ensuring the effective and efficient functioning of the healthcare system.
- Botswana, represented by BoMRA, has the potential to become a regulatory Center of Excellence, complementing existing Centers of Regulatory Excellence (RCOREs).



Centre of Regulaton RCORE ASSESSME How To Become Assessment o APPLICATION expression of a Designated interest. AU RCORE Submit an short-listing a expression of audits shall be Your country and/or interest to the conducted institution can **NEPAD** Agency accordingly become part of the AU RCORE. Just follow these four steps to get designated:

Key Players pillars of the development of Botswana's pharmaceutical industry







Parastatal companies

p.e., BVI, BotAsh, NARDI, BoMRA, BMC, etc.

Private companies



SMEs, startups, enterprises p.e., Portfolio Pharmaceuticals, Pyramid Pharma, Africure, etc.



Academy and R&D institutions

Universities (p.e. University of Botswana), R&D centres, etc.



1/3: Botswana can leverage the capacity and regional impact of its parastatal companies to develop the pharmaceutical sector











Botswana Ash (Pty) Ltd



National Agricultural Research and Development Institute



Botswana Meat Commission eat Perfection Defined





Vaccines for human & veterinary use

Pharmaceutical grade Raw materials & excipients from bovine origin

Botswana

Commission eat Perfection Defined

Meat

Pharmaceutical grade added-value & Regional market development



2/3: Botswana can leverage its SMEs, private enterprises & startups (private sector)



ORTHOSURGE BOTSWANA (PTY) LTD









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|-------|--|
| ••••• | Associated Fund Administrators people.passion.solutions |

PYRAMID

PHARMA







MEDI**Core**

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3/3: Elevating Innovation, the sector of the Academy and R&D institutions



Investing in the translation of R&D into product and services that impact the local and regional pharmaceutical industry

Translate research projects into patents, products & services, and companies







BUAN BOTSWANA UNIVERSITY OF AGRICULTURE AND NATURAL RESOURCES

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Creation of Centres of Excellence for Regional Cooperation and Development of Botswana's Pharmaceutical Sector



Short-term, mid-term and longterm investment opportunities

Short, mid and long term actions



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| No | Key Pillar | Potential Investment Target | Action |
|-------------|-------------------------------------|-----------------------------|---|
| 1 | Biopharmaceutical Products | Botswana Vaccine Institute | |
| Short-Term | | | Diversify product portfolio of veterinary vaccines. |
| Short-Term | | | Complete product portfolio selection of human vaccines. |
| Short-Term | | | Expand facilities to be able to manufacture human vaccines |
| Short-Term | | | Partner with other companies and research institutions |
| Medium-Term | | | Finish expansion of facilities for human vaccines. |
| Medium-Term | | | Get GMP certification of new facilities. |
| Medium-Term | | | Launch new veterinary vaccine. |
| Medium-Term | | | Start development of first project of human vaccines. |
| Long-Term | | | Complete clinical trials of the first human vaccine project |
| Long-Term | | | Hold GMP certification of manufacturing facility. |
| Long-Term | | | Target exporting to African market in general. |
| Long-Term | | | Launch first project of human vaccine. |
| 2A | Raw materials, excipients, salts | Botash | |
| Short-Term | | | Undertake a detailed feasibility study of the development pharmaceutical salts industry in Botswana |
| Medium-Term | | | Implementation of the manufacturing plan with the infrastructurer, production lines and processes, trial runs |
| Long-Term | | | Start production of the different qualities of a range of salts. |



Short, mid and long term actions



Reform for Investment & Sustainable Economies

| No | Key Pillar | Potential Investment Target | Action |
|-------------|---------------------------|-----------------------------|---|
| 2B | Medicinal plants | Medicinal plants producers | |
| Short-Term | | | Undertake a detailed feasibility study of development pharmaceutical herbal medicines industry in |
| | | | Botswana |
| Short-Term | | | Improving labeling, certifications, and overall product quality to meet the demands of local consumers. |
| Medium-Term | | | Looking for partnerships in R&D and development |
| Medium-Term | | | Emphasize value-added aspects such as essential oils to gain a competitive edge in the industry. |
| | | | Develop high-quality herbal medicines, nutraceuticals, and processed dietary supplements to meet |
| Long-Term | | | elevated standards in quality and processing techniques. |
| 2C | Raw materials, excipients | From bovine origin | |
| Medium Term | | | Undertake a detailed feasibility study of development bovine spin offs for the pharma industry in |
| Wedium Term | | | Botswana |
| 3 | Conventional Medicines | Repackaging Companies | |
| Short-Term | | | Promote companies' collaboration |
| Short-Term | | | Focus on Tablets |
| Short-Term | | | Diversify product portfolio. |
| Short-Term | | | Expand facilities to be able to do primary manufacturing, including in-house quality control |
| | | | laboratory |
| Medium-Term | | | Finish expansion of facilities |
| Medium-Term | | | Get GMP certification of new facilities |
| Medium-Term | | | Start primary manufacturing through backward integration |
| Medium-Term | | | Target local market first. |
| Long-Term | | | Target exporting to regional market. |
| Long-Term | | | Hold GMP certification of manufacturing facility. |
| Long-Term | | | Try holding product marketing registration without partnerships. |



Challenges and opportunities to develop Botswana's pharmaceutical Sector

7 challenges that restrict the development of the pharmaceutical sector in Botswana





1. Small local market & relying on imports mostly

2. Need of further commitment with investors and limited access to capital

3. Lack of specialized pharmaceutical manufacturing policies and incentives

4. Need of short programs to up-skill or re-skill Botswana's human capital

5. BoMRA has not yet achieved the WHO ML 3 status

6. Bran drain, lack of engagement with diaspora

7. Lack of transparency regarding data access for pricing, supply and demand of medicaments



7 strenghts that enable the development of the pharmaceutical sector in Botswana



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1. Accommodating tax policies: 15% tax for various players, 5-10 years tax holiday (0%) in some cases.

2. Freedom of capital movement and double taxation treaties with various major countries.

3. Promotion of procurement of local manufactured products

4. Special economic zone with adequate transport infrastructure.

5. BITC promotes and assists investment.

6. Large pool of public and private institutions to tap into.

7.Good quality of the regulatory body (BOMRA)



8 actions to unlock the pharmaceutical sector in Botswana



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1. Promote Transparency in supply, pricing, and demand data.

2. A one-stop shop entity to develop or address the specific needs of the industry.

3. Developing specialized policies and manufacturing for the pharmaceutical sector.

4. Monitoring, implementing, and driving the development of strategic industry subsectors.

5. Having a national strategy for the pharmaceutical sector and its subsectors for the next 5-8 years

6. Formal engagement with local, regional and international investors

7. Envisioning the sector as essential for Botswana's economy and diversification.

8. To establish GMP and quality standards for Botswana's pharmaceutical industry



In order for Botswana to establish itself in the pharmaceutical industry:



- 1. To specialize in sophisticated niche sectors
- 2. To boost local public, private sector partnerships, but also partnerships with global industry leaders to develop more sophisticated technologies or products
- 3. To start with a focus on human and veterinary vaccines
- 4. To work towards building a more diversified economy through developing the pharmaceutical sector as a major pilar for the economy
- 5. To prioritize a sustainable access to medicines through public health and economic benefits
- 6. A National Strategy to Develop Botswana's Pharmaceutical Sector



Big Thank you from our Africa Rise Team



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