Pharmaceuticals and medical devices sector

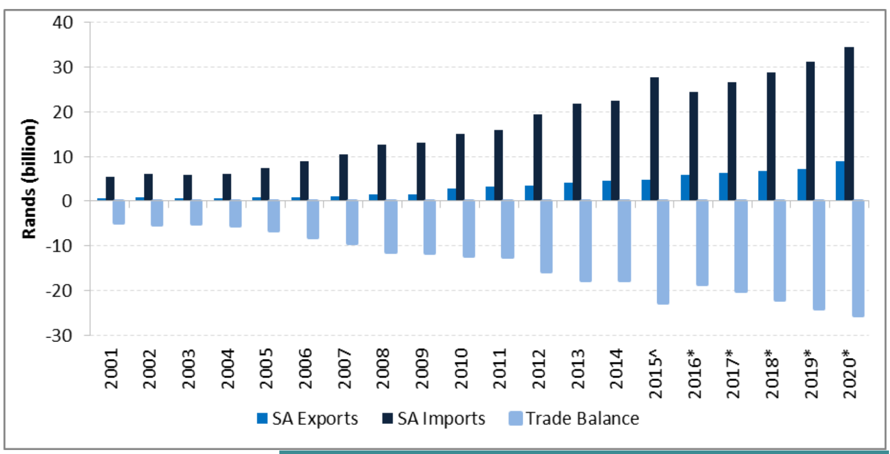
Situational Analysis: Pharmaceuticals

The global pharmaceutical market is worth US$300 billion a year and is expected to rise by 33,3% to US$400 billion by 2019. The United States of America is the dominant player in the market, owning six companies in the global top 10. North America, South America, Europe and Japan account for 85% the global pharmaceuticals market and this trend is expected to remain constant with their acquired advantage of increased economies of scale as well as patent protection, among other factors.

The South African pharmaceutical sector is the largest drug market in Africa, with the fifth highest expenditure on pharmaceuticals per capita. The total market value in 2015 was estimated at R44.0bn with R34.2bn (86.7%) attributable to the private healthcare market and R6.8bn (13.3%) to the public sector.

Figure 1 shows the value of South African exports and imports from 2001 to 2019 in Rands and US Dollars. South African pharmaceutical trade has always been characterised by higher levels of imports than exports, thus an increasing trade balance deficit. In 2015, pharmaceutical imports accounted for 85% of the country's total pharmaceutical trade, despite the depreciation of the rand against hard currencies. Asian and European markets remain the main sources of South Africa's pharmaceutical imports. However, the country's pharmaceutical exports have recently improved. In 2014, exports of pharmaceutical products amounted to R4 641 billion, showing an improvement from R3 323 billion in 2011. It is expected that by 2019 South African exports of pharmaceutical products will expand further to reach R7,1 billion. The country's exchange rate and productivity are the main factors that will assist South Africa in becoming more competitive in the global market.

Figure 1: South Africa's Trade in Pharmaceutical Products, 2001-2019



Data Extracted from: Trade Map, 2016; Quantec, 2016; BMI 2016a & BMI 2016b

The attractiveness of South Africa's pharmaceutical exports will depend on the efficiency of manufacturing firms and weakness of the exchange rate, which makes exports attractive. However, the weakened exchange rate might have an undesirable outcome as it may impact on the imports of active pharmaceutical ingredients (API), potentially raising the price of key medicines. Furthermore, the African continent has become the main destination for South African exports of pharmaceutical products and it is expected that more multinational corporations (MNCs) will continue using South Africa as a platform to explore the opportunities in the African market.

In terms of imports, despite the growth of the local manufacturing sector, the country continues to import most of its pharmaceutical products. The gap between imports and exports of pharmaceutical products continues to grow and imports are growing at a faster rate than exports. In 2015 pharmaceutical imports accounted for 85% of the country's total (two way) pharmaceutical trade, despite the depreciation of rand against global currencies. Imports of pharmaceutical products remain crucial in South Africa as the focus of the local manufacturers is on antiretroviral (ARVs) and other essential (generic) medicines. The international market remains the main source of other important products that are not yet manufactured nationally.

The country's export basket largely comprises medicament mixtures (mostly API), making up 70% of the total pharmaceutical exports in 2015, followed by medicament mixtures not for dosage at 11,3%. Medicament mixtures not for dosage have grown faster (40,7%) than other export categories, while exports of pharmaceutical goods, specified sterile products, sutures, luminarias have declined by a wide margin especially in 2015.

Notably, South Africa is the only country in the SADC that meets the Good Manufacturing Practice standards of the World Health Organization (WHO). Furthermore, the SADC free trade area ensures the country of tariff free exports. Thus, South Africa remains the main source of pharmaceutical products for various African states.

Approximately 276 companies are licensed by the DoH and the MCC to manufacture, import, export or distribute pharmaceuticals. Domestic manufacturing pharmaceutical companies almost exclusively produce generic products. SA pharmaceutical manufacturing companies are import dependent. According to ImpactRX, in 2015, the generics market in South Africa was valued at R11.7 bn (representing 35.3% of the market by value and 49.4% by volume). Originators medicines were valued at R16 bn, representing 48.2% of the market by value and 29.7% of the market by volume). The value of locally manufactured pharmaceuticals exported in 2015 was R billion.

High disease burden ensures increasing demand for drugs, especially anti-retroviral drugs. South Africa's rapid urbanization, sedentary lifestyles and dietary trends ensure long-term demand for pharmaceuticals that target chronic, lifestyle-related diseases.

Role-players in the sector believe that they can make a meaningful contribution to stimulating domestic growth and attracting foreign direct investment. The general consensus amongst the major pharmaceutical companies is an urgent need for policy certainty and consistency, a substantial reduction in the delays for products to be registered and support for local production together with strategic tariffs remedies and incentives to level the domestic playing field. Interventions targeted/focusing on the above issues to enable local manufacture needs to be considered to provide an incentive to grow the local manufacturing industry.

Key Opportunities

- Increasing local production of medicines
- Employment creation;
- Creation of new export and local market for local producers

Challenges facing the sector

Some of the core challenges facing the sectors' development have been highlighted below:

- Shortage of skills & required skill set in the Medicines Control Council and the excessively long period required for the registration of medicines through the MCC and the lengthy process required for the approval of clinical trials, are problems which have been facing the industry for many years.

- Currency weakness which increases the cost of imported active pharmaceutical ingredients (API's) which are key ingredients in the manufacturing process.
- Level of Single Exit Pricing (SEP) increases which do not adequately cover pharmaceutical companies cost base (of which currency is a substantial driver). SEP for pharmaceuticals makes this the only price regulated component of the private healthcare market. For an industry largely dependent on imported materials, the implementation of the SEP pricing and the annual adjustments does not have the flexibility to compensate manufacturers for significant shifts in exchange rate and other cost increases, causing a steady erosion of margins. Increasingly competitive government tenders, with punitive conditions attached for non-compliance, are of equal concern.
- Lack of transformation within the industry