

Sudan Pharma market which was worth \$ 451 million in 2014 is forecasted to reach \$ 491 million by the end of 2015 achieving a growth rate of 8.7%. The long term forecast for the market is put at \$ 645 million by 2019.

The local Government is keen on developing Pharma industry.

Latest Updates

- Egypt-based Pharma Overseas will invest USD500mn to set up a plant for the production of pharmaceutical raw materials in Sudan, according to Chairman Gamal Abdel Rahman in October 2015.
- Sudan and Chad renewed a health protocol between the two countries in September 2015. Sudanese Minister of Health Bahr Idriss Abu Garda re-affirmed Sudan's willingness to provide aid and support for the Chadian population.
- In November 2015, Vice President of Sudan, Bahri Hassan Saleh acknowledged that investing in the country's pharmaceutical market comes with difficulties. He confirmed that Sudan is seeking to increase the percentage of medicines supplied by local companies to 85%, up from the current 30%.

Structural Trends:

The value of Sudan's pharmaceutical market is somewhat disputed and there is no single universally accepted estimate. No data is available to distinguish the distribution of medicine sales between Sudan (North) and the now seceded (and UN-recognised) country of South Sudan. Expenditure and outlook assumptions and calculations are based on the value and growth potential of both countries combined. Regulatory and economic outlook is based on assessment of the dominant Sudan (North), which after secession has a population of 35.7mn, compared with smaller South Sudan, which has a population approaching 9.0mn.

Pharma Market

In 2014, we calculate that total pharmaceutical imports reached USD378mn. According to data from the International Trade Centre (ITC), imports of pharmaceuticals in finished dose form totalled USD279mn, while the value of pharmaceuticals in bulk form reached a value of USD37mn in 2014. These are active pharmaceutical ingredients (APIs), the majority of which are penicillin or streptomycin and derivatives. The APIs are then either distributed to pharmacies or packaged and sold in finished dose form. Sudan also imported USD62mn worth of other therapeutic commodities in the same year, the vast majority of which were vaccines.

As local pharmaceutical manufacturers operating in the country do not produce their own APIs, the packaging of imported ingredients represents the domestic industry's only contribution. Sudan exports an insignificant value of pharmaceuticals; imported products are therefore consumed within the country.

According to ITC data, over half of Sudan's pharmaceutical imports originated from India, Jordan, Switzerland, Egypt and France. It is forecasted that Sudan and South Sudan's imports of

pharmaceutical products would grow at a compound annual growth rate of 6.6%, and reach a value of USD521mn in 2019. This will be significantly higher than exports which we forecast to increase to USD0.67mn in 2019, from USD0.23mn in 2014 - corresponding to a compound annual growth rate (CAGR) of 23.3%.

Final selling price is 65% costlier than manufacturing price.

Communicable diseases dominate Sudan's disease burden, as is the case with the majority of Sub-Saharan African countries and the largest burden to Sudan's population are HIV/AIDS, malaria and diarrhoeal diseases. Measles and tuberculosis are also included in the top ten. According to the World Health Organisation, lower respiratory infections, diarrheal diseases and stroke are the three leading causes of death.

Currently, no major multinational drug makers produce medicines locally, instead preferring to supply the market via imports. GlaxoSmithKline, Roche and Novartis are all present through partnerships with local distributors. Hikma has a 22% market share (as of 2013) and produces locally, with Saudi drugmaker Tabuk also having a manufacturing presence. The leading Sudanese companies are Liliam Pharmaceutical Industries, Ami Pharma, Azal Pharmaceuticals and Blue Nile Pharmaceutical, with domestic producers supplying only a quarter of the market by value.

Regulatory Review

Sudan (North) has a semi-autonomous medicines regulatory authority, which was originally part of the Ministry of Health and is now known as the National Medicines and Poisons Board. South Sudan is establishing its own regulatory regime through its Ministry of Health. One area of concern for drugmakers is that Sudan and South Sudan are not members of the World Trade Organization (WTO).

All pharmaceutical products require marketing authorisation in Sudan. As of 2014, there were more than 5,000 pharmaceuticals registered in the country, and there are explicit criteria for applicants of marketing authorisation. There is a 12-month time limit for assessing a marketing authorisation.

All medicines facilities must also be approved for licensing from the regulatory authority. Technically, there is a requirement for manufacturers to comply with Good Manufacturing Practice (GMP), but the government has not published a locally applicable document. Inspectors are legally permitted to inspect premises where pharmaceuticals are produced or packaged. Equally, imports must be licensed by the authorities.

National Good Pharmacy Practice Guidelines are published by the Medical Council. The government has created regulatory provisions relating to the price of pharmaceuticals at manufacturing, wholesale and retail levels. However, it is unclear to what extent these regulations are followed or enforced and if the government does actively monitor national medicine prices.

There are legal provisions that prohibit the direct advertising of all medicines to the public, and pre approval is required for all medicines advertisements and promotional material. There is no national code of conduct regarding the advertising and promotion of medicines by marketing authorisation holders.

It is understood that Sudan FDA accepts applications for products registration only when the applicant has minimum 3 years old GMP certificate (to be reconfirmed)

Health Insurance:

Just over a third of the population is covered by health insurance, with the majority from the formal sector.

Health insurance is compulsory through the National Insurance Corporation Act (1994) for the formal sector, while it is voluntary for the informal sector and small companies. Coverage differs between states with the River Nile at 41% and South Darfur at only 11%. Over a third of health insurance funding is used on antibiotics and there are only 603 medicines included as part of the insurance scheme, corresponding to under a fifth of the total medicines registered in the country.

Procurement of medicines for the public in the north is run by the Central Medical Supplies Corporation (CMS), which is responsible for around 20% of medicine provision in value terms. While a programme to provide free medicines exists, this is only offered to children under five. There is no provision of free medication for patients unable to afford drugs or for more vulnerable patient groups, such as pregnant women and elderly patients. However, some medicines are provided free for specific communicable diseases - including malaria, tuberculosis and HIV/AIDs - as are vaccines from the expanded programme on immunisation (EPI). Free medicines are also provided in emergency cases, and there are also some public funds available for certain anti-cancer medications.

Epidemiology :

According to UNAIDS, the number of people living with HIV in Sudan is 53,000 \$ another 190,000 in south Sudan.

72% of the disease related deaths recorded in 2014 were due to malaria.

There are around 3 million people suffering with diabetes in Sudan & south Sudan.

Competition:

Currently, multinational manufacturers do not produce medicines locally or repackage pharmaceuticals, preferring instead to import their products through local distributors. GlaxoSmithKline and Roche both supply the market via DAL Medical Services, one of the leading pharmaceutical and healthcare distributors. Novartis supplies the market via Cisuba. Hikma is among the top foreign companies operating in Sudan with a 22% market share in 2013 and a portfolio of 73 products.

Indian companies , Gujarat Terce Laboratories and Jenburkt Pharmaceuticals are the leaders in generic sector.

Statistics:

India's export in \$ mn				
Category	2012-13	2013-14	2014-15	Gr%
Ayush	0.18	0.22	0.23	
Bulk Drugs & Drug Intermediates	21.78	21.58	18.77	-13.04
Drug Formulations & Biologicals	32.98	36.65	48.06	31.14
Herbals	0.01	0.01	0.04	352.95
Surgicals	0.32	3.33	2.28	-31.54
Vaccines	19.67	19.05	9.63	-49.47

SUDAN	74.94	80.84	79.01	-2.26
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