SUDAN PHARMA MARKET REPORT

Pharmexcil Hyderabad

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Demography

SL. No	Parameter	

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1	Region	Africa				
2	Country	Sudan				
3	Capital	khartoum				
4	Population	43, 120, 43 (July 2018 est.)				
5	Population growth rate (%)	2.93%(July 2018 est)				
6	GDP (purchasing power parity)	177.4 \$ Billion(2017 est)				
7	GDP - real growth rate (%)	1.4%(2017 est)				
8	GDP - per capita (PPP)USD	4,300 \$(2017 est)				
9	Exchange rates					
10	Population below poverty line	46.5%(2017 est)				
11	Age structure (%)	0-14 Years-43.07%				
		15-24 years 20.22%				
		25-54years and over: 29.8%				
		55-64 years 3.93%				
		65 & above 2.98%				
Source: CIA	Source: CIA World Fact Book updated to July 2018(On 22nd Dec 2018)					

Introduction

Sudan's currency devaluation has led to the shortage of a number of medicines, with some products also becoming completely unavailable for sale in the country. Sudan's industry needs to import active pharmaceutical ingredients (APIs) which makes market extremely vulnerable to currency fluctuations and external headwinds. Donations are likely to play an important role in the short to medium term, as the industry and operational risks continue to undermine any major pharmaceutical company activity.

Market was of \$ 533 million size in 2017, but due to heavy inflation market is forecasted to crash to \$ 184 million.

Latest Updates

- At the occasion of the World Mental Health Day in October 2018, Khaleej Times reported on the high prevalence of mental health issues and suicide attempts among the population within the conflict zone (affected by the ongoing South Sudan war), which had been highlighted by a Médecins Sans Frontières (MSF) doctor.
- In the same month, an East African Community (EAC) secretariat expert was quoted by IPP Media as saying the community is failing to provide adequate pharmaceutical coverage due to the lack of professionals in this field. The EAC, which covers Sudan and South Sudan, is working with the German organisation Deutsche Gesellshaft für Internationale Zusammenarbeit (GIZ) to improve capacities inthis area.
- Also in October, the governor of North Darfur State passed a decree that established a Humanitarian Aid Coordinative Office, which is affiliated with the state's Ministry of Health and Social Development.
- In late October and early November 2018, the UN Economic Commission for Africa (ECA) Office of North Africa (which covers Sudan), the Tunisian Ministry of Development, Investment and International Cooperation (MDICI) and the Tunisian Union of Industry, Trade and Handicrafts (UTICA) ran the 33rd Session of the Intergovernmental Committee of Experts (ICE), which examined individual country's statistical capabilities, with a view to building knowledge in this area that would underpin strategic planning. Some of the topics discussed during the event include the progress made towards the African Continental Free Trade.

Strengths

- Compared to many Sub-Saharan African pharmaceutical markets, Sudan's pharmaceutical market is large in value terms, albeit mainly due to its vast population.
- Strategic position favours medicine distribution between its neighbouring peers in North Africa and SubSaharan Africa.
- Relatively robust regulatory system, in comparison with its peers

Weaknesses

- Low government and out-of-pocket per capita health expenditure.
- Weak intellectual property laws.
- > Sudan and South Sudan are not members of the World Trade Organization.

Opportunities

- ➤ A large population is advantageous for long-term pharmaceutical demand.
- Investment from countries such as Nigeria, Turkey and Qatar should help raise the quality of healthcare provision and infrastructure.
- There is a growing presence of foreign generic drugmakers, including Indian and Middle Eastern pharmaceutical companies

Market

The outlook for Sudan's pharmaceutical market will continue to be affected by the prevailing economic and political environment. Sudan may not be on the radar of innovative Pharma

companies in the next Five to seven years, especially given the recent currency devaluation that has severely dented foreign currency market values.

In 2017, pharmaceutical expenditure is put at USD533mn, accounting for 8% of the country's healthcareexpenditure, or USD13 per capita. Exchange rate fluctuations will continue to negatively impact market growth in USDterms. Indeed, in 2018, the market will be worth USD184mn.

The devaluation of the Sudanese pound in H118is the reasonbehind the huge negative growth in USD terms. This undermines the overall size of the market and hasimplications on Sudan's domestic pharmaceutical manufacturers. Inflationarypressures will push up pharmaceutical import costs and thisposes a significant risk to domestic drugmakers as they rely raw material imports.

Forecast show that by 2022 market may reach a \$ 176 million with a negative cagr of 19.9%.

Currently, almost half the population is below the poverty line indicating a lopsided income distribution. Plans are underway to improve employment and other modes of increasing purchase capacity. This may take a while. Generics in these circumstances have betteropportunities.

Regulatory

Sudan 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.

In comparison to its regional peers, Sudan's regulatory regime is relatively well established. However, the fact that Sudan and South Sudan are not members of the World Trade Organization (WTO) is an considerable area of concern for innovative drugmakers.

All pharmaceutical products require marketing authorization in Sudan, of which there are explicit criteria for applicants. There is a 12-month time limit for assessing a marketing authorization and 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.

No legal provisions exist in the Sudanese Medicines and Poisons Act requiring pharmacovigilance activities as part of the medicines regulatory authority (MRA) mandate. The marketing authorization holder does not have to continuously monitor the safety of their products and report to the MRA. The national medicines and poisons board do stress the importance of pharmacovigilance activity, and a specific pharmacovigilance center linked to the MRA exists in Sudan. A laboratory exists in Sudan for the purpose of quality control testing, however the results are not made publically available.

Epidemiology

The burden of disease in Sudan and South Sudan is split fairly evenly betweencommunicable and non-communicable diseases.

According to UNAIDS, the number of people living with **HIV** in Sudan is 56,000, corresponding to a prevalence rate of 0.3% in adults aged between 15 and 49. In South Sudan, there are an estimated 180,000 HIV sufferers, which corresponds to a prevalence rate of 2.5%.

According to Globocan, the number of new cases of **cancer** in Sudan will increase from 20,355 in 2012 to 36,037 in 2030. Over the same time period, in South Sudan, this figure will increase from 8,688 to 15,462. Many cases are often undiagnosed or misdiagnosed, which is partly due to inadequate healthcare infrastructure and partly due to the widespread lack of awareness regarding the disease. According to Globocan, prostate cancer is the most common cancer in males, followed by Non-Hodgkin lymphoma, liver cancer and leukaemia. Breast cancer is the most frequent cancer in females, followed by cervical, ovarian and oesophagus cancer

According to the International Diabetes Federation (IDF), there were 1.4mn cases of diabetes in Sudan and South Sudan in 2015, with diabetes-related deaths reaching a value of over 22,000.

Neuropsychiatric disorders such as depression, epilepsy and Alzheimer's disease are causing an increasing burden in Sudan and South Sudan.

Local Industry

Currently, no major multinational drugmakers produce medicines locally, instead preferring to supply the market via imports. GlaxoSmithKline, Roche and Novartis are all present through partnerships with local distributors. Hikma 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 a lower proportion of the market by value

There is also a strong presence of foreign generic drugmakers, including Indian companies Taj Pharma, Gujarat Terce Laboratories and Jenburkt Pharmaceuticals.

Domestic Industry

There is a relatively significant domestic pharmaceutical industry in both Sudan and South Sudan, with 24 licensed pharmaceutical manufacturers operating in the market (according to latest available data from the Department of Production at the Ministry of Industry). However, the basic capabilities of the local drugmakers will make it difficult to achieve self-sufficiency and the supply of more sophisticated medicines will remain mandatory by imports. This current lack of capacity is highlighted by the fact that only 729 of the 5,000-plus registered pharmaceuticals are produced locally.

Statistics

India's exports

India's Pharmaceutical exports to SUDAN \$ Million						
2015- 2016- 2017- contbn Contbn to						Contbn to
Category	16	17	18	GR%	%	Region
BULK DRUGS AND DRUG						
INTERMEDIATES	20.52	18.96	23.90	26.06	30.60	6.10

DRUG FORMULATIONS AND						
BIOLOGICALS	43.01	32.34	42.02	29.92	53.79	1.62
AYUSH	0.42	0.39	0.46	17.53	0.58	2.57
				120.9		
Herbal Products	0.01	0.08	0.18	1	0.23	5.81
Surgicals	1.98	2.24	2.43	8.68	3.12	5.02
Vaccines	19.44	20.00	9.12	-54.41	11.67	3.09
Total	85.39	74.01	78.11	5.54	100.00	2.33

India's exports to Sudan During April-October \$ Mn						
Category	Fy-18	Fy-19	Change%	change in Revenue		
Bulk Drugs & Drug Intermediates	13.15	9.58	-27.18	-3.57		
Drug formulations & Biologicals	27.20	18.95	-30.35	-8.26		
Ayush	0.22	0.47	109.91	0.25		
Herbal Products	0.12	0.01		-0.11		
surgicals	2.01	1.11	-44.87	-0.90		
Vaccines	4.35	8.47	94.80	4.12		
Total	47.06	38.58	-18.01	-8.47		

Imports of Sudan

Top Ten Importing Partners of Sudan \$ Million						
Rank	Country	2015	2016	2017	Gr%	Share%
1	Jordan	76.06	72.90	148.96	104.33	14.77
2	India	66.57	64.16	130.73	103.76	12.96
3	Saudi Arabia	66.02	58.05	124.07	113.72	12.30
4	Switzerland	18.47	34.92	53.39	52.90	5.29
5	Egypt	33.32	30.66	63.99	108.68	6.34
6	China	29.01	30.61	59.62	94.79	5.91
7	Germany	20.55	24.84	45.40	82.73	4.50
8	United Arab Emirates	18.99	24.55	43.54	77.34	4.32
9	France	13.18	20.93	34.12	62.98	3.38
10	Pakistan	18.14	19.53	37.67	92.91	3.73
	World	501.61	507.11	1008.72	98.92	100.00