NIGERIA-PHARMA REPORT

The Nigerian Government has introduced Health-coverage scheme. However, private company micro insurance scheme has been more successful. These two schemes together will help drive demand for pharmaceuticals in the near future. Pharma market was of the size \$ 1.03 billion in 2014 and is forecasted to negatively grow by over 20% in 2015 and reach \$ 0.82 bn.

Key Trends:

In July 2015 the government's Common External Tariff (CET) has placed zero Tariff on imports of finished dosage forms and 5-20% of tariff on Pharmaceutical raw materials. This has become advantageous to India.

The Nigerian government plans to launch a community-based Social Health Insurance Programme in 84 locations across the country before the end of 2015. The move forms part of the government's commitment to provide access to healthcare services in rural areas and ensure an effective healthcare delivery system.

Strengths & opportunities

- One among more developed African nations.
- ➤ Government has launched NHIS(National health Insurance Scheme) expected to improve health care services for a long term.
- An aggressive campaighn by NAFDAC is having the positive impact on rducing the counterfeit drugs.
- ➤ Government aiming to introduce a patent regime that complies with the WTO's
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
- > Authorities and professional associations are making efforts to improve drug distribution and dispensing to reduce opportunities for counterfeiting.
- Government hoping to incentivise investment from Indian firms.

The Market:

In 2014, the pharmaceutical market was valued at USD1.03bn, representing 0.2% GDP and 4.8% of total health expenditure.

The market is expected to negatively grow by 5% cagr during the next five years ending 2019 and reaxh \$ 800 million value from the present \$ 1030 million in 2014.

Over-the-counter (OTC) medicines made up USD459mn, the largest part of the overall pharmaceutical market - at 44.5% of the total expenditure - followed by generic drugs with a 38.0% share, and finally patented drugs, with 17.5% of the market is the segmentation pattern.

An estimated 3.7% of the local population is living with HIV, and Nigeria has the second highest number of **new infections** reported each year globally. HIV/AIDS is a major financial burden in the country, with a domestic allocation of USD1.7bn to the President's Comprehensive Response Plan on HIV/AIDS (PCRP) for 2014-15. The government has committed a contribution of USD40mn, which the state governments are also expected to match. India's Pharma industry having entire range of Anti HiV drugs and exported at the most affordable prices stand a very good chance of fulfilling Nigeria's needs.

There are nine pharmaceutical and biotech companies listed on the Nigerian stock exchange. May & Baker is a local drugmaker which is currently in the process of completing the pre-qualification of its products from its WHO-standard manufacturing complex at Ota town in the Nigerian state of Ogun and has a collaborative relationship with Sanofi.

Generic Market

In Nigeria, 38% of the total market constitutes generics accounting for \$ 392 million in 2014. The market by 2019 with a negative cagr of 3.9% is likely to come down to \$ 3.21 million.

The local generic-focused manufacturing industry will benefit from government efforts to encourage the local production of anti-retrovirals (ARVs). Such initiatives have included the removal of tariffs for the raw materials used in the production of these treatments, and also the introduction of a state-subsidised programme to provide the drugs free of charge.

Nigerian government is trying to emulate South Africa, which has benefitted by encouraging local production of Anti-retroviral drugs, although the country is still hampered by its lack of patent protection. The government is aiming to have 70% of the country's pharmaceutical requirements produced domestically in the coming years.

Pharmaceutical Trade

Nigeria has a negative balance like most of the countries as far as Pharmaceuticals trade is concerned.

The key to attracting multinational investment would be a radical improvement of the national infrastructure or, at the very least, establishment of a zone where manufacturing could be concentrated. Imports will, remain key to meeting growing local demand for medicines. Pharmaceutical imports, which reached a value of USD318mn in 2014, are expected to negatively grow by 3.8% in to reach USD263mn by 2024, widening the country's pharmaceutical trade deficit from USD310mn in 2014 to USD219mn in 2019.

India is one of the leading suppliers of imports to Nigeria, with the authorities encouraging the participation of Indian firms. Nigeria accounts for about 25% of India's trade with Africa, making it India's biggest trading partner in the continent.

The Nigerian government has previously used pharmaceutical import bans to force domestic drug makers to increase production. While the only drugs banned are those currently manufactured locally, there is simply not enough capacity to meet aggregate demand, leaving prices for any available medicines prohibitively high for the majority of the population. Speculation over another selected import ban on medicines in Nigeria has been mounting, especially in light for the drive towards self-sufficiency. Previous such experiences have so far failed to yield results.

Regulatory

The main regulatory body in Nigeria is the National Agency for Food and Drug Administration and Control (NAFDAC). The country's pharmaceutical regulatory infrastructure is inadequate, providing no meaningful patent legislation or pricing and reimbursement systems

NAFDAC works with the Nigeria Ports Authority (NPA), which is required to release shipping and cargo manifests to NAFDAC inspectors. All factories must be certified for good manufacturing practices (GMP) before they are allowed to import drugs into Nigeria and NAFDAC must inspect factories anywhere in the world before it registers or renews the registration of their products. The agency also requires compulsory pre-shipment information from all importers before the arrival of their products.

The Standards Organisation of Nigeria (SON) announced in November 2014 that discussions were in the final stages to ensure that all products imported into the country from 2015 onwards will carry the Nigerian Industrial Standard (NIS) mark. This is part of the efforts to prevent counterfeit medicines entering the local market and threatening the health of patients and the commercial activities of local manufacturers. Currently only locally manufactured products carry this mark.

Product registration fees for imported ethical (generic) drugs stand at USD2, 200, and USD10, 000 for each over-the-counter (OTC) product. The fee for prescription drugs breaks down as USD77 for a permit to import, USD1,081 for processing and USD772 for the registration certificate. Additionally, each formulation (such as capsule and tablet) and dosage of the drug requires separate registration, which means that the processes are lengthy (estimated to last as long as three years).

Statistics:

India's Exports of Nigeria in \$ mn							
Category	2012-13	2013-14	2014-15	Gr%			
Ayush	1	1	1	11.36			
Bulk Drugs & Drug Intermediates	47	43	43	-1.21			
Drug Formulations & Biologicals	257	277	310	12.02			
Herbals	0	0	0	269.05			
Surgicals	0	5	4	-13.37			
Vaccines	35	58	59	2.47			
Grand Total	341	384	418	8.77			
Source: DGCIS							

Nigeria is the fifth largest export Destination of India's Pharmaceuticals.

Imports:

Value in USD mn							
Formulations Imports of Ukraine							
Rank	Countries	2011	2012	2013	% growth	Contbn	
1	India	119.24	116.32	139.12	19.60	44.44	
2	China	51.01	34.78	45.11	29.68	14.41	
3	Switzerland	25.86	31.40	35.19	12.04	11.24	
4	United Kingdom	17.67	29.72	24.42	-17.85	7.80	
5	Belgium	13.67	9.40	8.95	-4.84	2.86	
6	Germany	1.12	4.03	6.18	53.43	1.97	
7	Ireland	2.35	7.62	5.54	-27.32	1.77	
8	Indonesia	0.00	0.62	5.15	731.30	1.65	
9	Slovenia	2.99	4.85	4.48	-7.65	1.43	
10	France	15.12	6.63	4.42	-33.41	1.41	

	World	400.91	307.23	313.05	1.89	100.00
Source: UN comtrade						