Pharmaceutical Sector Profile: Nigeria

Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries

UNITED NATIONS
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PHARMACEUTICAL SECTOR PROFILE
Nigeria

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Strengthening the local production of
essential generic drugs in least developed and
developing countries

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
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FOREWORD

Providing adequate health care to their populations remains a major challenge for governments in Africa. Unsatisfactory and inadequate access to essential drugs and other healthcare commodities is a key limitation that impacts on people's health in most developing and Least Developed Countries (LDCs).

The increased funds now available for the procurement of medicines to treat the three pandemics (HIV/AIDS, malaria and tuberculosis) are a very valuable development and have reduced the suffering and extended the lives of millions of people in developing regions. However, reliance on donor funds is clearly not sustainable in the long term and there are many other diseases for which pharmaceuticals are key treatments and for which access to quality medicines is much less advanced. In response to these considerations, the African Union, subregional organizations such as the Southern African Development Community (SADC), and various individual countries in Africa have identified the local production of essential drugs as an important component of a long term solution to the provision of adequate healthcare in developing countries.

Adequate access to drugs is dependent on both the affordability and quality of the products. Unaffordable drugs are clearly not the solution but, equally, affordable low quality products are not the answer either. Therefore, an industry that produces high quality drugs at competitive prices must be the target when developing local manufacture of pharmaceuticals in Africa.

The pharmaceutical sector is a complex one, involving many different stakeholders such as the manufacturers themselves, national regulators, government ministries, wholesalers and others. Developing the industry requires concerted action across these stakeholders to create the environment in which that industry can flourish and realize its full potential as an asset to economic and social development. An example of the role of different stakeholders can be seen with regard to the scourge of counterfeit drugs, which cause huge health problems and also represent a threat to legitimate manufacturers who effectively have to compete with these substandard products.

In the face of this situation, actions by, for example, regulators to reduce the penetration of these counterfeit products would, as well as being important from a health perspective, also benefit the local pharmaceutical industry. Furthermore, quality requires upgraded skills and equipment, so how can high quality products be produced at affordable prices? This challenge requires various government ministries to work together to establish the support to the industry that will enable efficient local companies to invest in high quality production. However, those companies that do invest in upgrading will need some form of protection from those that wish to produce products at a lower standard. Consequently, the establishment and enforcement of quality standards by regulators is a critical element in solving the conundrum.

Since 2006, UNIDO, with funding from the Government of Germany, has been conducting a project on strengthening the local production of essential generic drugs in developing and Least Developed Countries. The objective is to help the pharmaceutical sectors in developing countries realize their potential role of acting as a pillar of public health and contributing to economic and social development.

The project has carried out a number of different initiatives and will be continuing and expanding on this work in the future. This series of reports, which describe the local pharmaceutical industry in individual countries is one such initiative. They provide a comprehensive picture of the status and operating environment of the pharmaceutical sector and are designed to assist national level stakeholders and inform discussions on how local production fits into the strategy for improved supply of medicines. In parallel, this information will inform the ongoing debate among the international development community on the local manufacturing of generic medicines in closer proximity to where they are actually needed.

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ACRONYMS

ACPR	Adequate Clinical and Parasitological Response
ACT	Artemisinin Combination Therapy
AFBTE	Association of Food, Beverage and Tobacco Employees of Nigeria
AIDS	Acquired Immune Deficiency Syndrome
AMFm	Affordable Medicines Facility - malaria
ANCLA	Association of Nigerian Licensed Customs Agents (*sic*)
API	Active Pharmaceutical Ingredients
ARFH	Association for Reproductive and Family Health
ARIPO	African Regional Intellectual Property Organization
ART	AntiRetroviral Treatment
ARV	AntiRetroViral
BMI	Business Monitor International
BMR	Batch Manufacturing Report
BPP	Bureau of Public Procurement
CAC	Corporate Affairs Commission
CACFAO	Codex Alimentarius Commission of the Food and Agricultural Organization
CB	Community Based
CEO	Chief Executive Officer
CET	Common External Tariff
cGMP	Current Good Manufacturing Practice
CIDA	Canadian International Development Agency
CMS	Central Medical Stores
DF	Damien Foundation
DFID	Department for International Development
DOTS	Directly Observed Treatment, Short-course
ECOWAS	Economic Community of West African States
EDL	Essential Drug List
EMVHS	Essential Medicines, Vaccines and Health Supplies
ENR	Enhancing Nigeria Response to HIV/AIDS
EOHSI	Environmental and Occupational Health Science Institute
EU	European Union
FDC	Fixed Dose Combination
FEPA	Federal Environmental Protection Agency
FMoH	Federal Ministry of Health
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GFATM	Global Fund to fight AIDS, TB and Malaria
GLRA	German Leprosy and TB Relief Association
GMP	Good Manufacturing Practice
GSK	Glaxo Smith Kline
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization
HPLC	High Performance Liquid Chromatography
HSS	Health System Strengthening
ICCM	Inter-Agency Coordination Committee for Malaria
IEC	Information, Education and Communication
IPAN	Institute of Public Analysts of Nigeria
IPPA	Investment Promotion and Protection Agreement
IPT	Intermittent Preventive Treatment

ITN	Insecticide-Treated Net
JICA	Japan International Cooperation Agency
JSI	John Snow Inc.
LDC	Least Developed Country
LGA	Local Government Area
LLIN	Long Lasting Insecticidal Net
MAN	Manufacturers Association of Nigeria
MCH	Maternal and Child Health
MCMC	Malaria Case Management Committee
MD	Managing Director
MDG	Millennium Development Goals
MDR-TB	Multi Drug Resistant Tuberculosis
MIS	Medicines Information System or Management Information System
MVA	Manufacturing Value Added
NACA	National Agency for the Control of AIDS
NAFDAC	National Agency for Food and Drug Administration and Control
NAGAFF	National Association of Government Approved Freight Forwarders
NCC	Nigerian Copyright Commission
NCPP	National Council on Public Procurement
NOTAP	National Office for Technology Acquisition and Promotion
NBS	National Bureau of Statistics
NCD	Non Communicable Diseases
NCPP	National Council on Public Procurement
MDCN	Medical and Dental Council of Nigeria
NDF	National Drug Formulary
NDP	National Drug Policy
NDLEA	National Drug Law Enforcement Agency
NEEDS	National Economic Empowerment Development Strategy
NEPC	Nigerian Export Promotion Council
NGMP	Nigerian Good Manufacturing Practices
NGN	Nigerian Naira
NGO	Non-Governmental Organization
NHIS	National Health Insurance Scheme
NHP	National Health Policy
NICOYS	Nigerian Community of Young Scientists
NIMR	Nigerian Institute of Medical Research
NIPC	Nigerian Investment Promotion Commission
NIPO	Nigerian Intellectual Property Organization
NIPRD	National Institute for Pharmaceutical Research and Development
NIROPHARM	Association of Nigerian Representatives of Overseas Pharmaceutical Manufacturers
NLR	Netherlands Leprosy Relief
NMA	Nigeria Medical Association
NMCP	National Malaria Control Programme
NNMDA	Nigerian Natural Medicine Development Agency
NOTAP	National Office for Technology Acquisition and Promotion
NPR	National Patent Registry
NTBLCP	National TB and Leprosy Control Programme
NTDs	Neglected Tropical Diseases
OTC	Over the Counter
OVC	Orphans and Vulnerable Children
PATHS	Partnership for Transforming Health Systems
PCN	Pharmacists Council of Nigeria

PCT	Patent Cooperation Treaty
PDA	Personal Digital Assistant
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary Health Care
PLT	Patent Law Treaty
PLWHA	People living with HIV/AIDS
POM	Prescription only Medicines
PMCT	Prevention of Mother to Child Transmission
PMG	Pharmaceutical Manufacturing Group
PPMDA	Patent and Proprietary Medicine Dealers Association
PMG-MAN	Pharmaceutical Manufacturing Group of Manufacturers' Association of Nigeria
PSM	Procurement and Supply Management
PSN	Pharmaceutical Society of Nigeria
QC	Quality Control
R&D	Research and Development
RBM	Roll Back Malaria (Partnership)
RFID	Radio Frequency Identification
RMRDC	Raw Materials Research and Development Council
SCMS	Supply Chain Management System
SFH	Society for Family Health
SMEDAN	Small and Medium Enterprises Development Agency of Nigeria
SP	Sulphadoxine/Pyrimethamine
SON	Standards Organisation of Nigeria
SWOT	Strengths, Weaknesses, Opportunities, Threats
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNDCP	United Nations Drug Control Programme
UNDP	United Nations Development Programme
UNICEF	United Nations International Children's Emergency Fund
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration
VCT	Voluntary Counselling and Testing
WAHO	West African Health Organization
WADRAN	West African Drug Regulatory Authorities Network
WAPMA	West African Pharmaceutical Manufacturers Association
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

The key challenges confronting Nigeria's pharmaceutical market include counterfeit medicines, poor healthcare infrastructure and the limited spending power of citizens. The pharmaceutical market was estimated to be worth US$ 600 million in 2009 and should grow substantially at around 12 per cent year-on-year to reach US$ 717 million by 2011. Despite government efforts to promote domestic manufacturing, Nigeria remains heavily reliant on imported pharmaceuticals. The revised National Drug Policy (NDP) (2004) set a target for 70 per cent (in volume) of the country's demand for medicines to be met by local drug manufacturers by 2008. Consequently, Government policies support local production of essential medicines in accordance with the NDP.

The pharmaceutical manufacturing sector has experienced a steady annual growth of 10 per cent to 15 per cent since 2001 (IFC). Furthermore, some local drug manufacturers are currently upgrading their facilities to comply with WHO prequalification and WHO cGMP requirements. If successful, this will enable them to promote the export of medicines manufactured locally in Nigeria to ECOWAS countries and beyond. In addition, once prequalified, local manufacturers will be able to participate in international procurement tenders called by international development partners. Consequently, the 70 per cent target set in the National Drug Policy should be achievable within the next 10 years.

The current Government in Nigeria has embarked on an ambitious agenda to become one of the top 20 economies of the world by the year 2020 and this is its No. 1 priority. Undoubtedly, such an initiative will impact positively on the whole industrial sector, including local production of pharmaceuticals, and will also boost Nigerians' purchasing power to acquire medicines.

The procurement of medicines in Nigeria is influenced by economic globalisation, the participation of stakeholders in the medicine supply chain (WHO and Federal Ministry of Health, 2007), multiple manufacturing sites for the same producer, the presence of extensive illicit markets, fake and substandard products and poor storage infrastructure.

Most of Nigeria's health indicators are poor and it will be impossible for the country to meet most of the targets for the Millennium Development Goals (MDGs) by 2015. The challenges facing the health sector include the failure of Government to play an effective stewardship role, fragmented health service delivery, inadequate and inefficient financing, weak health infrastructure, inefficient distribution of the health workforce and poor coordination amongst key players.

According to the survey conducted in the framework of this report, there are about 120 local drug manufacturers in Nigeria. Capacity utilization within the sector is about 40 per cent, meaning that there is a large volume of under utilized manufacturing capacity which could be applied to produce new products upon demand. According to the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN), about 60 per cent of pharmaceutical production in ECOWAS countries is located in Nigeria. Technical skills, trained manpower and basic manufacturing infrastructure already exist. Thus, Nigeria has the potential to establish itself as the leading manufacturer and distributor of essential medicines in sub-Saharan Africa.

The survey further indicated that poor infrastructure (power, water, transportation) increases the cost of medicine manufacture and distribution whilst also hampering growth. Currently, no Nigerian pharmaceutical manufacturer has attained WHO cGMP (current Good Manufacturing Practice) requirements and WHO prequalification although some companies are – *inter alia* – upgrading their facilities and hope to attain this status in the near future. However, for the time being, they cannot participate in international tenders for pharmaceutical supplies and their scope for exporting is also limited. Attainment of WHO cGMP and prequalification status will enable local pharmaceutical producers to participate in international tenders for supplies of antiretrovirals, antimalarials and anti-TB medicines. A further obstacle faced by local manufacturers is access to finance for working capital and upgrading facilities, which is constrained by high bank interest rates.

Nonetheless, the survey did reveal some opportunities for the pharmaceutical industry. For example, the existing large market size in Nigeria, strong demand and the need for management of infectious diseases (especially HIV/AIDS, malaria, TB, and "neglected childhood diseases") constitute an opportunity. Furthermore, increased Research and Development (R & D) efforts at the National Institute for Pharmaceutical Research and Development (NIPRD) and in universities could lead to new formulations, therapeutic agents, nutraceuticals and phytomedicines to be developed from the abundant indigenous biodiversity and traditional medicine in Nigeria.

Sustained economic growth in recent years and macroeconomic stability will promote poverty reduction and greater purchasing power. The increasingly visible and active medicines regulatory authority, the National Agency for Drug Administration and Control (NAFDAC) will increase consumer confidence in available medicines and possibly raise their marketability. Furthermore, regulatory harmonization (in progress) through the West African Drug Regulatory Authorities Network (WADRAN) will promote trade within the West African subregion. A further opportunity lies in the trade incentives for pharmaceuticals introduced by the Economic Community of West African States (ECOWAS) to promote the movement of pharmaceuticals within the subregion. In addition, the establishment of the West African Pharmaceutical Manufacturers Association (WAPMA), which aims to strengthen regional medicine production, will promote increased collaboration and trade.

The ban on importation of some essential medicines, for which there is adequate local capacity and technical skills, will promote local production of essential medicines and the establishment of the National Health Insurance Scheme (NIHS), with a target of providing universal healthcare coverage by 2015, will provide funds for these essential medicines.

However, the survey also highlighted some threats to the pharmaceutical sector. The unacceptable level of poverty and related lack of purchasing power severely undermine the market for locally produced medicines. Furthermore, informal open air markets selling medicines in unauthorised premises constitute a threat to the *bona fide* local industry. The stigma of substandard health products affects international marketing of medicines produced in Nigeria. Another threat is the uncontrolled and chaotic medicine distribution system and parallel imports. Furthermore, local manufacturers have to cope with pervasive corruption within the system.

Yet, in spite of the weaknesses and threats identified, the pharmaceutical industry in Nigeria has grown at an average annual rate of between 10 and 15 per cent over the last five years (PMG-MAN, 2010). This positive development may have been stimulated by rigorous Government policy on the promotion of local drug production. During the preparation of this

report, it was observed that six companies had commenced upgrading or building of new facilities in preparation to meet WHO prequalification requirements. If the companies are eventually certified, this will further promote local production, given the increased opportunity to participate in international tenders. In addition, WHO prequalification may promote marketing of medicines produced by such companies beyond Nigeria and throughout the West African subregion due to increased confidence in the quality of their products.

1. INTRODUCTION

1.1 Background and Objective

The task of ensuring the population's access to quality essential medicines at affordable prices is among the prime challenges facing many governments in the management of public health systems in developing countries. In recent years, considerable progress has been made, with support from The Global Fund to Fight Aids, Tuberculosis and Malaria (GFATM), in the supply of essential medicines to combat these three major diseases. In most cases, public health services are limited to a few treatment centres whilst people in rural areas may have no functional centres with trained staff and medicines. In reality, most people have to pay for the limited healthcare services available to them. Consequently, access to essential medicines is very limited due to the cost and restricted availability of quality essential medicines in rural poor communities.

In some developing countries, the local capacity, the economic situation and relatively small population mean that local production of essential medicines is not a viable proposition. However, in Nigeria a population of over 140 million represents a huge potential market and local expertise and experience in the manufacture of essential medicines exist. Large markets increase the possibility that economies of scale can be achieved in the production process meaning that essential medicines can be sold at affordable prices. Consequently, the commercial prospects for local drug manufacture are positive.

The purpose of this report is to provide a review and analysis of pharmaceutical manufacturing capability in Nigeria, its operating environment, and its ability to provide medicinal products for the priority diseases of HIV/AIDS, malaria, tuberculosis and neglected tropical diseases.

A systematic presentation of baseline information on the pharmaceutical sector in Nigeria is given, together with information on current key demand/supply-side constraints impeding local production of essential generic medicines. Trends and operational challenges and policy issues related to the production of essential generic medicines in Nigeria will be reviewed and analysed. The report will look at interventions for increased local manufacturing of essential generic medicines currently employed in Nigeria. The report also makes an assessment of the prospects for the successful promotion of expanded, commercially viable, local production of quality essential generic medicines with some recommendations on how this can be achieved according to PMG-MAN included in Annex 1.

1.2 Overview of Nigeria's economic structure and the role of the manufacturing sector

Nigeria has a land area of about 923,773 square kilometres, a population of about 140 million people and a per capita income of some US$ 988 per year (2007). Administratively, the country has six geopolitical zones, 36 States and a Federal Capital Territory which ranks as a State, and 774 local Government Areas. There are at least 37 major cities and several relatively large rural communities that account for at least 60 per cent of the population but which are highly deprived of essential amenities.

Nigeria shares a 4,047 km border with Benin, Niger, Chad, and Cameroon and has a coastline of at least 853 km. In 1991, the national capital was relocated to the city of Abuja in the centre of the country. Prior to this, the national government was administered from the coastal city of Lagos, which still remains the commercial capital. On 1 October 1960, Nigeria gained its independence from the United Kingdom.

Nigeria is one the most densely populated countries in Africa. National census results in recent decades have been disputed but the most recent census by the Government of Nigeria (2006) recorded a population of 140,003,542, with 71,710,459 (51.2 per cent) men and 68,293,083 (48.8 per cent) women. Over 60 per cent of the population lives in rural areas and the average annual population growth rate is 2.3 per cent (World Bank Development Report, 2010). The 2006 population census estimated that 42.3 per cent of the population is between 0 and 14 years of age, while 54.6 per cent is between 15 and 65 years of age; the birth rate is significantly higher than the death rate, at 40.4 and 16.9 per 1000 people respectively.

Gross Domestic Product (GDP) at current prices in 2005 stood at US$ 212 billion according to the National Bureau of Statistics, while the annual growth rate of GDP was 5.3 per cent in 2008 (World Development Indicators Data, World Bank, 2009). The public sector is quite large in Nigeria and government spending accounts for some 27 per cent of GDP. The industrial sector is estimated to have contributed an average of 43 per cent of GDP over the last five years but this includes the massive oil and gas sub-sectors, which alone account for over 90 per cent of total industrial activity.

Nigeria's private manufacturing sector is relatively small and the share of manufacturing in GDP is around 4 per cent. In a move to promote manufacturing, the Federal Government has introduced various protective measures, including a ban on imports of certain products and, since 2000, 40 products have been added to the list of banned items.

1.3 Basic health data on Nigeria

Table 1 shows health data on Nigeria (Frost & Sullivan, 2009). The country's health system was ranked 187th out of 191 member states by the World Health Organization (WHO) in 2000. The Government has acknowledged that the healthcare system is poorly organised and resourced and that this has contributed to an overall decline in health status indicators over the past decade. According to the Federal Ministry of Health (FMoH), life expectancy at birth is currently estimated at 46 years for males and 47 years for females, while the under-five mortality rate is estimated at 19 per cent (Table 1). In comparison, estimates for life expectancy in Ghana and South Africa are: 55 and 59; 50 and 52 years for males and females, respectively. Under-five mortalities in Ghana and South Africa were estimated at 112 deaths per 1000 and 67 deaths per 1000 respectively (WHO: Mortality Country Fact Sheet 2006).

Table 1: Nigeria - Basic Health Indicators

Description	*Measurement*
Total fertility rate (2003)	5.7 children
Life expectancy at birth for males	46 years
Life expectancy at birth for females	47 years
Infant mortality (per 1000 live births), 2006	115
Under-five mortality (%)	19.4
Full vaccination coverage (children aged between 12 months and 23 months), 2003	13.0%
HIV prevalence (Adults aged more than 15 years)	3.5%
Number of medical personnel, 2006	403,457
Doctors (per 100,000 population), 2006	30
Nurses (per 100,000 population), 2006	100

Source: Frost & Sullivan, 2009

1.4 Priority Diseases

Infectious diseases continue to be the leading causes of morbidity and mortality in Nigeria (Table 2). The revised National Health Policy (2005) identified target areas for government intervention to include HIV/AIDS, malaria, diarrhoea, immunization coverage, onchocerciasis (river blindness), tuberculosis and reproductive health. HIV/AIDS, malaria and tuberculosis are prevalent diseases in Nigeria and treatment is unaffordable for the majority of the population.

Table 2: Contribution to Morbidity

	Disease conditions	*Contribution*
1	HIV/AIDS	16.0%
2	Respiratory diseases	14.0%
3	Malaria	11.0%
4	Cardiovascular diseases	10.0%
5	Childhood diseases	9.0%
6	Diarrhoeal diseases	7.0%
7	Injuries (Road accidents, drowning, violence)	7.0%
8	Perinatal conditions	4.0%
9	Others (cancer, urinary diseases, TB, etc)	22.0%

Source: Federal Ministry of Health, Abuja, 2010

1.4.1 Malaria

Malaria is responsible for 60 per cent of all outpatient attendance, 30 per cent of all hospital admissions and 300,000 deaths annually (FMoH, 2010). Artemisinin Combination Therapy (ACT) is the first line treatment in accordance with the national malaria treatment guidelines. The cumulative prevalence rate for malaria infection in most parts of the country is 100 per cent in any 10 month period. It is estimated that at least 10 per cent of all childhood deaths are due directly to malaria and up to 25 per cent indirectly. As of 2003, the volume of economic output lost because of incapacity through malaria was estimated at 4 per cent of GDP per annum (Amos Petu, 2004). Undoubtedly, malaria is one of the principal causes of morbidity and mortality in Nigeria and imposes an enormous socio-economic burden on the country.

1.4.2 Tuberculosis (TB)

TB is a major public health problem in Nigeria with the country ranking fourth among the 22 high TB burden countries which collectively account for about 80 per cent of the global burden of TB. According to the FMoH, the number of TB cases notified in the country increased from 31,264 in 2002 to 90,307 in 2008. There are some 374,000 estimated new cases annually. In view of the magnitude of the burden of TB in Nigeria, the Federal Ministry of Health declared TB to be a national emergency in 2006. The public health burden posed by TB is becoming increasingly onerous as the country's HIV/AIDS epidemic unfolds. WHO estimates that more than a quarter of new TB patients are HIV positive. Collaborative TB-HIV/AIDS services are being scaled up and the number of TB patients tested for HIV increased from about 7,500 in 2006 to 27,850 in 2007 (FMoH, 2010).

1.4.3 HIV/AIDS

According to a UNAIDS Report published in 2009, the HIV prevalence in Nigeria has been steadily contracting from 5.8 per cent in 2001 to 3.1 per cent in 2007. This is a much lower figure than in other African countries, such as South Africa and Zambia, but the size of the population means that by the end of 2009 there were 3.3 million Nigerians living with HIV (AVERT). Nigeria is one of 15 focus countries, which collectively represent 50 per cent of HIV infections worldwide.

Table 3 below shows estimates of HIV among adults and children between 2005, 2006 and 2010. Although the estimate of those infected who need ART differs from the UNAIDS estimate, the table is important as is emphasises the magnitude of the gap between those who need ART and those receiving ART. It also indicates the increasing trend in the number of HIV positive births, underlining the additional challenge of preventing mother-to-child HIV transmission. It is estimated that only 5 per cent of the population can afford ARVs without any additional financial assistance, while 15 per cent can afford them with some support and 80 per cent cannot afford them at all.

Table 3: HIV Estimates for Nigeria

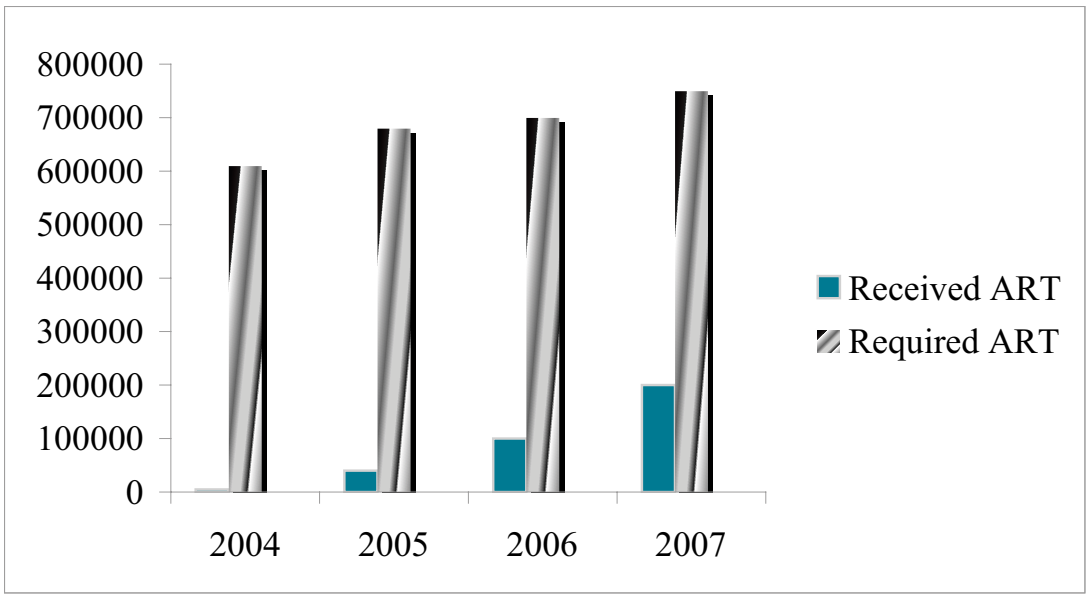
	2005	*2006*	*2010*
Number of people infected	2,860,000	2,990,000	3,400,000
Number of new HIV infections: • Adults • Children (under 15 years)	296,320 73,550	305,080 74,520	346,150 75,780
Number requiring ART • Adults • Children (under 15 years)	412,450 94,990	456,790 98,040	538,970 106,840
Annual HIV positive births	73,550	74,520	75,780
Cumulative deaths	1,450,000	1,700,000	2,820,000

Source: Federal Ministry of Health, 2010

It is therefore not surprising that there was a progressive increase in the number AIDS-related deaths from 1.45 million in 2005 to 2.82 million (projected) in 2010. In view of this situation, the majority of PLWAs in Nigeria need support from Government and international development partners if they are to regularly access ARVs. As of the end of 2009, 312,000 of those living with AIDS/HIV received antiretroviral therapy (ART), representing about 26 per cent of all those who need treatment. The Government has set an ambitious goal of providing ART to 694,000 people living with AIDS (PLWAs) by the end of 2011. Between 2005 and 2009, AIDS related deaths fell from 220,000 to 170,000 per year.

The estimated number of people receiving antiretroviral therapy (ART) between 2004 and 2007 compared with those who needed the treatment is shown in Figure 1 below. The number of treatment sites increased from 71 (2005) to 215 (2007).

Figure 1: Number of PLWAs who received ART compared with those who needed it



*Source: UNAIDS, 2009 Note: the vertical axis represents the number of PLWAs.

2. THE PHARMACEUTICAL MARKET IN NIGERIA

2.1 Market size

According to the 2006 National Census, the population of Nigeria was 140 million and thus constitutes potentially the largest domestic market in Africa. A large proportion of the population suffer from both infectious and non-infectious diseases but their purchasing power is weak given the level of poverty.

Estimates of the size of the pharmaceutical market in Nigeria vary significantly. In 2009, the Pharmaceutical Manufacturing Group of the Manufacturers' Association of Nigeria (PMG-MAN) estimated the size of the total pharmaceuticals and healthcare products market to be in excess of US$ 2 billion annually. The estimated market for prescription ethical pharmaceuticals is US$ 500 million and that for over the counter (OTC) pharmaceuticals about US$ 900 million. Furthermore, PMG-MAN estimates the Nigerian market for biological products (including vaccines, insulin, interferon, etc.) to be worth about US$ 100 million. In addition, related healthcare and lifestyle products account for about US$ 500 million.

Business intelligence services estimate the pharmaceutical market in Nigeria at US$ 600 million (Business Monitor International BMI 2010) for 2009. Out of this figure, BMI attributes the largest share of US$ 418 million to generic medicines, US$ 121 million to over the counter (OTC) products and US$ 61 million to patented products. Frost & Sullivan estimated a pharmaceutical market value of US$ 740 million in 2009. Out of this figure, US$ 266.4 million were attributed to generic medicines, US$ 177.6 million to branded products and US$ 296 million to OTC products (Frost & Sullivan 2010).

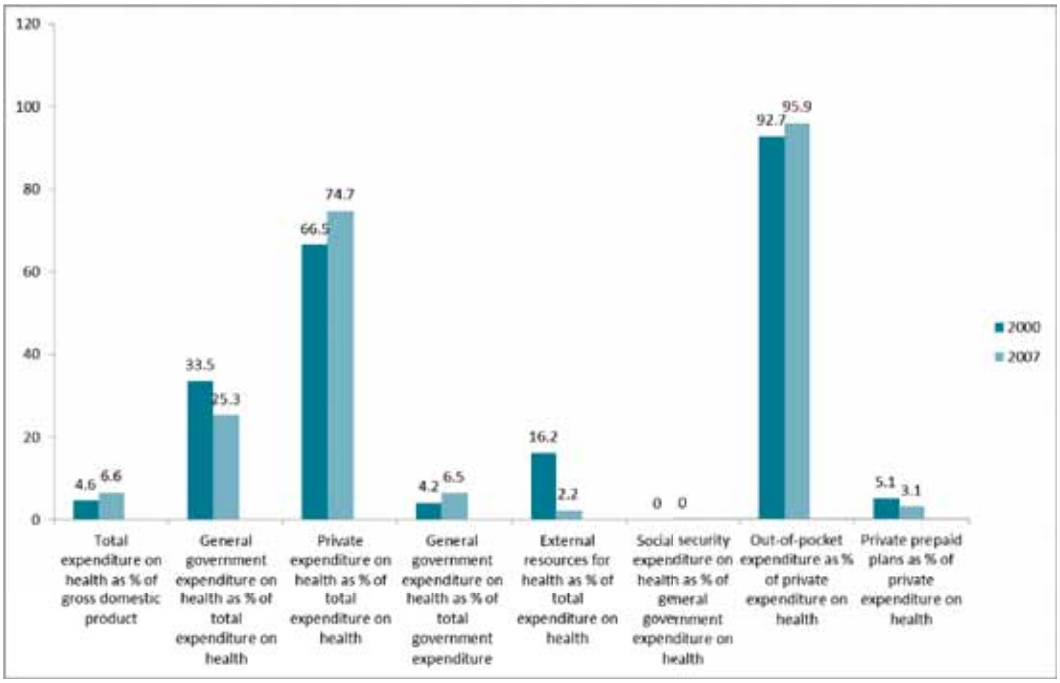
Nigeria also provides 60 per cent of the health products consumed in the Economic Community of West African States (ECOWAS) by volume (PMG-MAN, 2010) and, with an estimated population of about 600 million, the ECOWAS subregion represents a huge potential market.

2.2 Healthcare financing

In line with the growth in both private and public expenditures, funding for healthcare services increased from US$ 1,842.6 million in 1995 to US$ 5,382.7 million in 2007 (Source: World Health Organization, 2010). Donor funding remains a major source of healthcare funding in Nigeria and has increased at a Compound Annual Growth Rate (CAGR) of 44.2 per cent from 1995 to 2007. It should be noted that funding levels fluctuate on an annual basis.

Figure 2 shows that 74.7 per cent of expenditure on health is made by the private sector, underlining the low contribution of Government to the health sector. Out-of-pocket expenditure was 95.9 per cent of all private expenditure on health. There was no social security expenditure on health by Government in 2007. However, these statistics are expected to change over time as the National Health Insurance Scheme is now operational.

Figure 2: Nigeria - Health Expenditure Ratios



Source: World Health Statistics, World Health Organization, 2010

The National Health Insurance Scheme (NHIS) was established under Act 35 of 1999 by the Government of Nigeria and operationalized in 2005. This is a bold attempt by Government to increase access to healthcare and to reduce the burden on public healthcare facilities. Currently, however, only Federal public servants and their families benefit from the scheme although there are plans to widen access to other population groups. It is anticipated that the NHIS will become the main instrument for funding healthcare in Nigeria over the next few years.

2.3 Treatment of malaria, tuberculosis and HIV/AIDS and its funding

A significant share of funding to fight the three pandemics is provided by The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund or GFATM). Total Global Fund aid disbursed for malaria, HIV/AIDS, and TB programmes between 2005 and 2009 amounted to US$ 1,226,147,435 and, according to the policy of the Country Coordinating Mechanism for the Global Fund, about 60 per cent of the funds are used for medicine procurement.

Table 4: Approvals and Disbursements by the Global Fund for Rounds 2, 4 and 5 Portfolios in Nigeria

Grant	*Name of PR*	*Grant start date*	*Total Approved Funds (US$)*	*Actual Disbursements to date (US$)*
HIV Round 5 Phase 2	ARFH	01/01/07	26,406,149	15,378,638
HIV Round 5 Phase 2	NACA	01/01/07	110,679,776	72,699,420
HIV Round 5 Phase 2	SFH	01/01/07	24,093,914	12,560,992
Malaria Round 4 Phase 2	SFH	01/01/08	30,641,591	25,670,296
Malaria Round 4 Phases 1 & 2	YGC	01/01/05	43,900,696	38,481,707
TB Round 5 Phase 2	ARFH	01/01/07	38,170,420	11,994,538
Malaria Round 8 Phase 1	NMCP	01/11/09	101,526,897	78,066,740
	YGC	01/11/09	105,783,083	85,580,403
	SFH	01/11/09	77,596,646	48,402,067
HSS Round 8 Phase 1	NACA	01/11/09	55,379,935	20,975,288
HIV/AIDS Round 9	Ongoing		341,019,908	
TB Round 9	Ongoing		113,332,101	

PR: Principal Recipient; ARFH: Association for Reproductive and Family Health NACA: National Agency for the Control of AIDS; NMCP: National Malaria Control Programme; SFH: Society for Family Health; HSS: Health System Strengthening; YGC: Yakubu Gowon Centre

Source: Society for Family Health, 2010.

The following disease-specific sub-sections give some additional information about the treatment schemes in place and the main sources of funding.

2.3.1 Malaria

The World Health Assembly 58 Resolutions (May 2005) set as one of their targets the establishment of national policies and operational plans to ensure that at least 80 per cent of those at risk of malaria benefit from major preventive and curative interventions by 2010. This resolution was based on a WHO technical recommendation which proposed a target of reducing the burden of malaria by at least 50 per cent by 2010 and by 75 per cent by 2015.

In addition, the African Summit on Roll Back Malaria (RBM) held in Abuja, Nigeria in April 2000 demonstrated a real convergence of political momentum, institutional synergy and technical consensus on malaria. A Declaration and Plan of Action were adopted at the end of the Summit. Among others, the following targets were set to be reached by 2005:

- At least 60 per cent of those suffering from malaria should be able to access and use affordable and appropriate treatment within 24 hours of the onset of symptoms

- At least 60 per cent of those at risk of malaria, particularly pregnant women and children under five years of age, should benefit from suitable personal and community protective measures such as Insecticide Treated Nets (ITNs)
- At least 60 per cent of all pregnant women who are at risk of malaria, especially those in their first pregnancies, should receive intermittent preventive treatment (IPT)
- The malaria mortality rate in Africa should be halved

The therapeutic efficacy of antimalarials is shown in Table 5. The survey of Chloroquine and Sulphadoxine/Pyrimethamine (SP) was undertaken in 2002, while the ACT study was done in 2004 and based on adequate clinical and parasitological response parameters. The table indicates that Sulphadoxine/Pyrimethamine was surprisingly effective in the North Western part of Nigeria. Evidently, the most effective ACT is the Artemether/Lumefantrine combination, which is the treatment of choice against malaria.

Table 5: Therapeutic Efficacy of Antimalarial Medicines in Nigeria - Adequate Clinical and Parasitological Response (ACPR)

	Zones	*Chloroquine**	*Sulphadoxine/ Pyrimethamine**	*Artemether/ Lumefantrine***	*Artesunate/ Amodiaquine***
1	South East	3.7%	14.9%	100%	100%
2	South South	9.1%	8.5%	87%	82.5%
3	North Central	53.2%	82.7%	100%	96%
4	North West	77.3%	94.2%	100%	100%
5	South West	40.9%	75.6%	100%	100%
6	North East	50.8%	64.8%	100%	100%

* 2002 Drug Efficacy Study ** 2004 Drug Efficacy Study

Source: National Policy on Malaria Diagnosis and Treatment, Federal Ministry of Health, Abuja, 2010.

The most recent version of the National Policy on Malaria Diagnosis and Treatment indicates that injections of Quinine Dihydrochloride, Artemether and Artesunate are the medicines of choice for severe attacks of malaria (Tables 6 and 7).

Table 6: Medicines of Choice in the Treatment of Malaria

Medicines	*Dosage form*	*Presentation*	*Strength*
Artemether-Lumefantrine	Tablet	Co-formulated	20mg Artemether + 120mg Lumefantrine per tablet
Artemether-Lumefantrine	Dispersible (children)	Co-formulated	20mg Artemether + 120mg Lumefantrine per tablet

Source: National Policy on Malaria Diagnosis and Treatment, Federal Ministry of Health, Abuja, 2010.

Table 7: Current Medicines for the Treatment of Severe Malaria

Medicines	*Dosage form*	*Strength*
Quinine Dihydrochloride	Injection	300mg/ml in 2ml ampoule
Artemether	Injection	80mg/ml in 1ml ampoule
Artesunate	Injection	60mg/1ml vial
Artesunate*	Suppository	50mg suppository

* Suppositories if Artesunate is used only as pre-referral treatment

Source: National Policy on Malaria Diagnosis and Treatment, Federal Ministry of Health, Abuja, 2010.

Table 8 shows the partners involved in supporting malaria treatment in Nigeria between 2005 and 2009. The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) has had a profound impact on the fight against malaria. In 2008, 7,455,680 doses of Sulphadoxine/Pyrimethamine (SP) were distributed compared with only 1,912,581 doses between 2005 and 2007.

In respect of ACT, the greatest contributor in 2010 was also the Global Fund (28,521,700 doses), followed by the World Bank (15,982,157 doses). In line with the Millennium Development Goals, the Governments of Nigeria and the People's Republic of China committed to supply 1,425,617 and 432,000 doses of ACT respectively.

Table 8: Partners Providing Malaria Commodities

Organization	*Support provided*
GFATM	SPs distributed between 2005/2007 are 1,912,581 doses
GFATM	2010 ACTs for distribution through NMCP as PR are 7,826,355 doses
GFATM	2010 ACTs for distribution through YGC as PR are 8,145,796 doses
GFATM	2010 ACTs for distribution through SFH as PR are 12,549,549 doses
GFATM	ACTs for 2010 are 28,521,700 doses
GFATM	ACTs distributed between 2006/2007 are 13,516,593
WB	WB procured 2,000,000 doses of ACT in 2009
WB	Committed 15,982,157 doses of ACT for 2010
SuNMaP	Initially projected 2,000,000 doses of ACT in 2010 but current commitment not known
Federal Government of Nigeria	ACTs distributed 2008/2009 - Adult doses are 1,425,617
Federal Government of Nigeria	ACTs-Child are 2,440,023 in 2008
Federal Government of Nigeria	SPs distributed 2008 are 7,455,680
Federal Government of Nigeria	Long Lasting Insecticidal Nets (LLINs) distributed are 327,280 in 2008
Chinese Government donation to GoN	432,000 doses of ACT in 2009

PR: Principal Recipient; NMCP: National Malaria Control Programme; SFH: Society for Family Health; SP: SuNMap: Support to Nigeria Malaria Programme; YKC: Yakubu Gowon Centre.

Source: National Malaria Control Programme, FMoH, Abuja, 2010

The Malaria Case Management Committee in the Federal Ministry of Health is responsible

for the selection of ACTs in accordance with the National Guidelines on the Treatment of Malaria, which were last revised in 2004. In the public sector, ACTs are purchased, stocked at the Federal Medical Stores at Oshodi in Lagos State and distributed to health centres throughout the country using distribution agents. Only about 15 per cent of the population can afford to purchase ACTs on their own, 30 per cent can afford them with some assistance, and 55 per cent need to obtain them free of charge (FMoH, 2009).

This situation underlines the immense significance of the support from Government and development partners in providing ACTs and ITNs free of charge. However, local drug manufacturers are unable to participate in the Global Fund scheme since none of them is currently WHO prequalified and they are thus not able to compete in international tenders financed, *inter alia*, by the Global Fund.

Obtaining prequalification status is particularly important in view of the Global Fund's launching of The Affordable Medicines Facility – malaria (AMFm) which procures only prequalified medicines. The AMFm promotes the use of ACTs through the public, private and NGO sectors. This will save lives and reduce the use of less effective monotherapy treatments to which malaria parasites are becoming increasingly resistant. The Facility is an innovative financing mechanism with the objective of reducing the price differential between ACTs and other antimalarials even though ACTs are six to ten times more expensive than the older antimalarials. AMFm Phase 1 is now being implemented through nine pilots in eight countries, including Nigeria.

The Global Fund, as host and manager of the AMFm, has negotiated with drug manufacturers to reduce the price of ACTs and to require that sales prices must be the same for both public and private sector first line buyers. In July 2010, a Master Supply Agreement was signed between the Global Fund and six international pharmaceutical manufacturers - Ajanta Pharma, Cipla, Guilin, Ipca, Novartis and Sanofi-Aventis for supplying ACTs to first line buyers under the AMFm.

Private importers now pay up to 80 per cent less than they did in 2008-2009. The Global Fund pays most of this reduced price (a 'buyer co-payment') directly to manufacturers to further lower the cost to eligible first line buyers of ACTs purchased from manufacturers. This means that first line buyers only pay the remainder of the sales price for the ACTs and they are expected to pass on the highest possible proportion of this price benefit so that patients are able to buy ACTs across the public, private, not-for-profit and for-profit sectors at prices that are less than those of oral Artemisinin monotherapies and competitive with the prices of Chloroquine (CQ) and SP.

Currently ACTs make up only 5 per cent of treatments provided through the private sector in Nigeria. However, the reduction in price achieved through the new facility will enable some 60 per cent of malaria patients who obtain treatment in private shops to access the most effective treatments at affordable prices. For patients who currently pay for treatment, this is expected to result in a significant reduction in the price from about US$ 6-10 per treatment to about US$ 0.20-0.50.

The immediate effect of the AMFm initiative is affordability of ACTs for patients who need them, with improved quality of life and prevention of unnecessary deaths from malaria. However, PMG-MAN views the initiative as a threat to the local industry, especially the 11 companies which are manufacturing ACTs locally. According to the industry it is important that some local drug manufacturers should be able to participate in the AMFm initiative as

suppliers because the real challenge lies in sustainability after the initiative comes to an end. To address this problem and to ensure continued ACT supply in the long run it would be advantageous if ACTs could be sourced locally, even under the AMFm. To fulfil the quality requirements, five local drug manufacturers have already commenced upgrading/building their facilities to meet WHO prequalification and certification requirements.

2.3.2 Tuberculosis (TB)

According to the Society for Family Health, an amount of US$ 39,807,996 was approved by the Country Coordinating Mechanism Committee of development partners supporting the TB programme in Nigeria for 2010. The international community provides significant support for TB control in Nigeria. The National TB and Leprosy Control Programme (NTBLCP) coordinates and provides strategic direction for TB control activities in Nigeria. It is noteworthy that under the NTBLCP more than 450,000 TB cases have been successfully treated free of charge since 2005 in Nigeria. This is necessary because, according to the Ministry of Health, only about 5 per cent of the population can afford anti-TB medicines on their own. Furthermore, about 35 per cent of TB patients can afford the medicines if supported, while 60 per cent cannot afford them at all.

In April 2009, the Nigeria Stop TB Partnership was launched to support Government efforts in advocacy and mobilisation of additional resources from the private sector and multilateral organizations for the control of TB in Nigeria. The goal of the National TB programme is to reduce TB prevalence and death rates by 2015 to 50 per cent relative to their 1990 level. Directly Observed Treatment, Short-course (DOTS) coverage has increased rapidly from 55 per cent in 2002 to 91 per cent in 2007 and, although still far short of WHO's target of 70 per cent, the TB case detection rate increased from 11 per cent in 2002 to 23 per cent in 2007. The Stop TB Partnership provides technical support, assists with fundraising, and provides drugs through the Global TB Drug Facility to provide direct technical support to the NTBLCP. The main partners assisting with DOTS implementation are the Tuberculosis Control Assistance Programme, the German Leprosy and TB Relief Association (GLRA), the Damien Foundation (DF), the Netherlands Leprosy Relief (NLR), the UK's Department for International Development (DFID), the Canadian International Development Agency (CIDA), and the International Union against Tuberculosis and Lung Disease. These organizations provide support for training, supervision, logistics, equipment, and drugs. In 2006, the Global Fund to Fight AIDS, Tuberculosis and Malaria approved a Round 5 grant of US$ 25.8 million to support TB and TB-HIV/AIDS activities in Nigeria. These funds are focused on improving TB case detection and outcomes.

Tables 9 and 10 below show the treatment regimes for TB in adults and children respectively.

Table 9: Treatment Regimes for New Adult Cases using Fixed Dose Combinations (FDCs): 2RHZE/6EH or 4RH

		Pre-treatment weight		
Regimen	***> 70kg***	***55-70kg***	***38-54kg***	***30-37kg***
Intensive phase: daily supervised for two months - combined tablet of RHZE (150mg + 75mg + 400mg + 275mg) – 4FDCs	5	4	3	2

	Pre-treatment weight			
Regimen	**> 70kg**	**55-70kg**	**38-54kg**	**30-37kg**
Continuation phase: daily for six months (monthly collection) - combined tablet of EH (400mg + 150mg)	2	2	2	1
OR				
Continuation phase: daily supervised for four months - combined tablet of RH (150mg + 75mg)	5	4	3	2

Key: E=Ethambutol (400 mg); H=Isoniazid (100 mg); R= Rifampicin (150 mg); Z= Pyrazinamide (400 mg)

Source: Federal Ministry of Health, Abuja, 2010

Table 10: Treatment Regimes for New Children's Cases using Fixed Dose Combinations (FDCs): 2RHZ/6RH or 4RH

	Pre-treatment weight			
Regimen	**15-19kg**	**10-14kg**	**8-9kg**	**< 8kg**
Intensive phase: daily supervised for two months - combined tablet of RHZ (60mg + 30mg + 150mg)	3	2	1 ½	1
Continuation phase: daily for six months (monthly collection) - combined tablet of TH (50mg + 100mg)	2	1	½	½

Remark: If a child is HIV-positive, TH should be replaced with RH daily supervised for four months at the same dosage as during intensive phase.

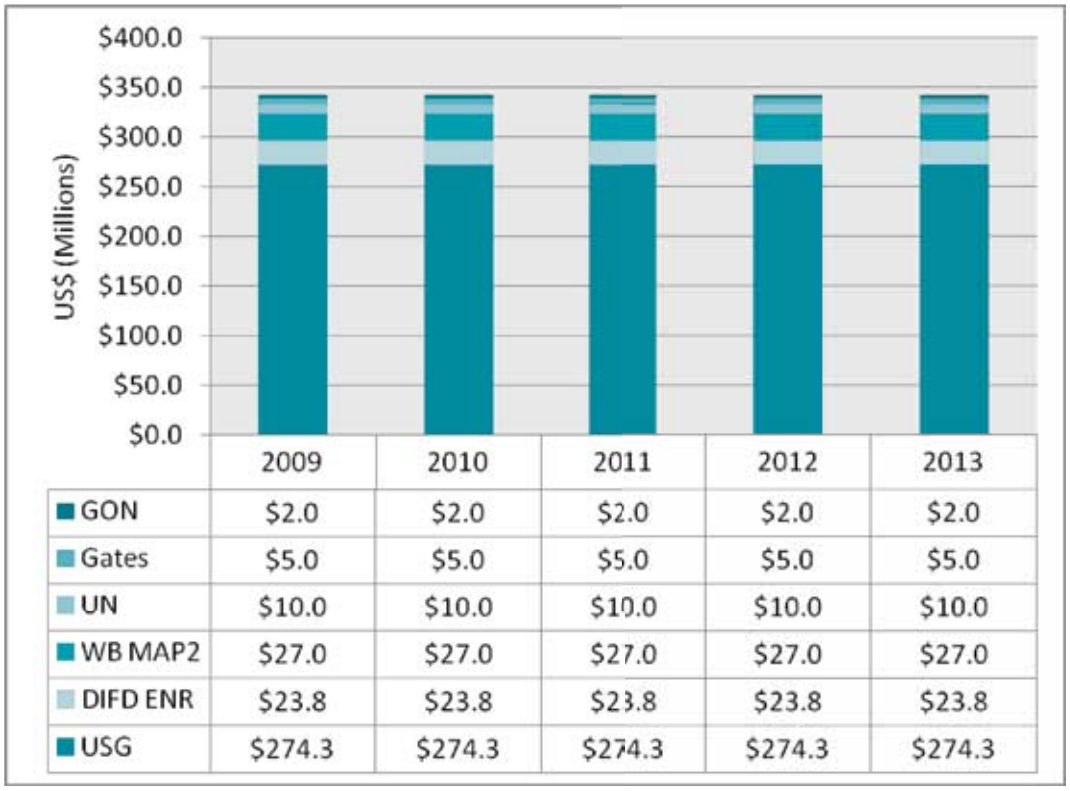
Source: Federal Ministry of Health, Abuja, 2010

2.3.3 HIV/AIDS

The expected value of funding for HIV/AIDS programmes from the Government of Nigeria (GoN) and from major bilateral and multilateral organizations is depicted in Figure 3. It is assumed that the US Government (through the President's Emergency Plan for AIDS Relief - PEPFAR) would sustain funding up to 2014 at the same level as that obligated in 2009.

PEPFAR is the largest contributor of financial resources for HIV programmes in Nigeria and in 2007 it supported 83 per cent of the ART programme. The UK's Department for International Development (DFID)'s Enhancing Nigeria Response project has committed US $23.8 million (8.7 per cent) annually for the period 2009 to 2013 for the fight against HIV/AIDS. It is expected that the GoN will spend US$ 47.7 million annually on HIV/AIDS programmes from 2010 to 2014. Similarly, the Gates Foundation has pledged US$ 5.0 million per year for five years.

Figure 3: Funding Sources for HIV/AIDS Programmes



	2009	2010	2011	2012	2013
GON	$2.0	$2.0	$2.0	$2.0	$2.0
Gates	$5.0	$5.0	$5.0	$5.0	$5.0
UN	$10.0	$10.0	$10.0	$10.0	$10.0
WB MAP2	$27.0	$27.0	$27.0	$27.0	$27.0
DIFD ENR	$23.8	$23.8	$23.8	$23.8	$23.8
USG	$274.3	$274.3	$274.3	$274.3	$274.3

Source: National Agency for the Control of AIDS, Federal Ministry of Health, Abuja, Nigeria, 2010.

According to the National Agency for the Control of AIDS (NACA), the cost of HIV/AIDS services, if maintained at 2009 levels through to 2014, would be some US$ 530 million to US$ 650 million per year with prevention, care, and treatment constituting 35 per cent, 20 per cent and 45 per cent of the total cost respectively.

In order to continue scaling up HIV/AIDS services over the next five years, an additional US$ 113 million per year is needed and this would give a total annual funding level of US$ 1.1 billion by 2014. According to NACA, over US$ 2.5 billion per year will be needed to achieve universal coverage throughout the country and the scaling up of services will require funding not only for direct provision of services but also for the development of infrastructure for training and retraining of health workers. The present level of funding is only 11 per cent of what is needed for universal coverage of prevention, care and treatment and the possibility of innovative funds mobilization strategies, including cost-sharing mechanisms, grants, private contributions, and increasing national contributions needs to be explored.

Table 11 shows the proposed framework for scaling up antiretroviral therapy (ART) in Nigeria.

Table 11: Framework for scaling up ART in Nigeria

	Baseline	*2004 - 05*	*2005 – 06*	*2006 – 07*	*2007- 08*	*2008 - 09*
People on treatment	35,000	200,000	300,000	450,000	600,000	1,000,000
Cost (US$ Millions)	25.97	148.40	222.60	333.90	445.20	742.00
Unit cost per patient per year = US$ 742. 00						

Source: Federal Ministry of Health, 2010

The first line antiretroviral combination was Stavudine, Lamivudine and Nevirapine but this was subsequently changed to Zidovudine, Lamivudine and Nevirapine because of side effects from Stavudine.

Table 12 shows the list of ARVs registered with NAFDAC, including the classes, names, formulations and manufacturers.

Table 12: Antiretrovirals (ARVs) registered with NAFDAC

Class	*Drug name*	*Strength*	*Manufacturer*
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)	Zidovudine (ZDV)	Tabs 300mg	Ranbaxy, GlaxoSmithKline (GSK), Fidson, Sai Mirra, Aurobindo
		Caps/Tabs 100mg	GSK, Ranbaxy, Boehringer
	Lamivudine (3TC)	Caps 150mg	Pharmacare, Ranbaxy, GSK, Sai Mirra, Cipla, Emcure, Aurobindo, Strides, Hetero, Fidson
	Lamivudine (3TC)	Caps 100mg	GSK
	Abacavir (ABC)	Tabs 300mg	M & B, Evans, Ranbaxy, GSK
	Tenofovir (TDF)	Tabs 300mg	Patheeneen
	Didanosine (ddI)	Tabs 50mg	Bristol-Myers Squibb (BMS)
		Tabs 100mg	Ranbaxy
		Tabs 150mg	BMS
		Tabs 200mg	Ranbaxy, BMS
	Stavudine (d4T)	Caps 20mg	Bristol Myers
		Caps/Tabs 30mg	Ranbaxy, Cipla, Aurobindo, Strides, Fidson, BMS
		Caps/Tabs 40mg	Pharmacare, Ranbaxy, Cipla, Emcure, Hetero, Aurobindo, Strides, Fidson, BMS
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)	Nevirapine (NVP)	Tabs 200mg	Evans, Cipla, M&B, Ranbaxy, Emcure, Strides, Aurobindo, Hetero, Boehringer, BMS
	Efavirenz (EFV)	Caps 200mg	Janssen (Ranbaxy), Emcure, Hetero, Cipla, Merck
		Caps 600mg	Ranbaxy, Aurobindo, Emcure, Hetero, Cipla, Fidson

Class	*Drug name*	*Strength*	*Manufacturer*
Fixed dose combinations (NNRTI/NRTI)	ZDV + 3TC + NVP	Tabs 300mg + 150mg + 200mg	Cipla, Pharmacare, Ranbaxy, Aurobindo, Fidson, Hetero, Plethico
	ZDV + 3TC	Tabs 300mg + 150mg	Drugfield, Evans, Ranbaxy, Meditab, GSK, Cipla, Strides, Aurobindo, Emcure, Fidson, Hetero.
	3TC + ZDV + EFV	Tabs 150mg + 300mg + 600mg	Aurobindo
	ABC + ZDV + 3TC	Tabs 300mg + 300mg + 150mg	Ranbaxy, GSK
	3TC + ABC	Tabs 80mg+600mg	GSK
	TDF + FTC	Tabs 300mg+200mg	Patheon
	d4T + 3TC + NVP	Tabs 30mg + 150mg + 200mg	Archy, Cipla, Hetero, Aurobindo, Strides, Ranbaxy, Fidson
	d4T + 3TC + NVP	Tabs 40mg +150mg + 200mg	Cipla, Hetero, Strides, Ranbaxy, Fidson, Yangzhou
	d4T + 3TC + EFV	Tabs 30mg + 150mg + 600mg	Ranbaxy, Emcure
	d4T + 3TC + EFV	Tabs 40mg + 150mg + 600mg	Ranbaxy, Emcure, Pharma/Daveon
	d4T + 3TC	Tabs 30mg+150mg	Ranbaxy, Cipla, Strides, Fidson
		Tabs 40mg+150mg	Ranbaxy, Cipla, Strides, Fidson
		Tabs 20mg+150mg	Aurobindo
Fixed dose combinations (NRTI/PI)	ZDV + 3TC + Indinavir	Caps 200mg + 150mg + 40mg	Gosun

Source: National Guidelines for HIV and AIDS Treatment and Care in Adolescents and Adults, FMoH, Abuja, 2010.

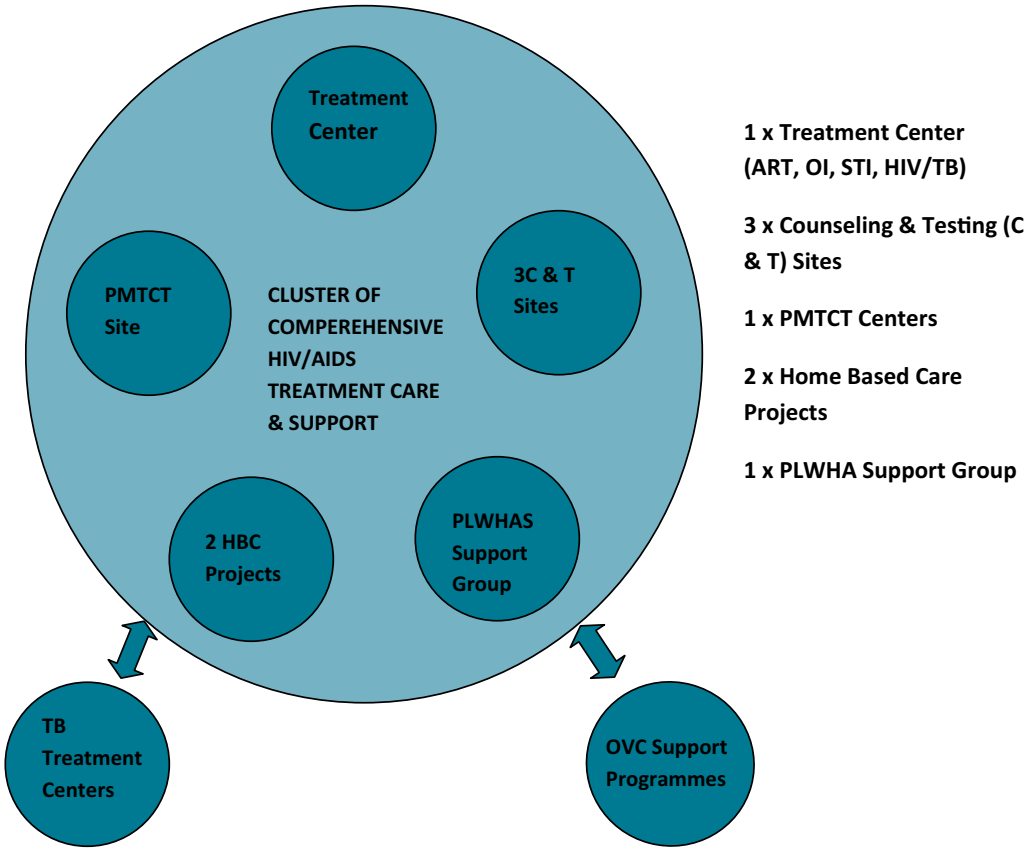
Nigeria's National Agency for the Control of AIDS (NACA) has introduced a harmonized approach to the management of HIV/AIDS by adopting the integrated cluster model (Figure 4).

The main objectives of this initiative are:

- To expand comprehensive HIV/AIDS treatment, care and support for People Living with HIV/AIDS (PLWHA) in the country's 36 states and the Federal Capital
- To expand access to HIV Testing and Counselling in the country's 36 states and the Federal Capital
- To strengthen the role of the community, civil society organizations and networks of PLWHA in providing and supporting HIV/AIDS treatment and care
- To increase access to care and support services for Orphans and Vulnerable Children (OVC) in the 36 states and the Federal Capital
- To increase the capacity of the private sector to implement work place HIV/AIDS programmes in 12 states

- To strengthen the capacity of implementing institutions for effective programme management, coordination, monitoring and evaluation

Figure 4: Cluster of Comprehensive HIV/AIDS Treatment, Care and Support



The limited implementation of this cluster model in 2009 pointed to promising signs of improvement in the effective coverage of the treatment of HIV/AIDS as well as the prevention of vertical transmission from mother to child. People were treated against opportunistic infections, AIDS, sexually transmitted diseases and TB at treatment centres. The success of this model will promote the use of the approved medicines for the infections indicated above. This expansion of the market will open up opportunities for the six local drug manufacturers currently preparing for WHO prequalification. If successful, these firms will be able to compete in procurement exercises carried out by international development partners.

2.4 Supply of pharmaceuticals

The Government (including Federal, State and Local Government Areas) supplies pharmaceutical products to its various health institutions. The Federal Government is responsible for policy formulation and technical guidance to all healthcare providers. In addition, the Federal Government supplies drugs and medical supplies to tertiary healthcare centres (University Teaching Hospitals) and Federal Medical Centres located in all the 36 states. The State Government is responsible for providing healthcare to State hospitals as well as offering technical support to the Local Government Areas (LGAs). The LGAs take care of healthcare services at primary healthcare level. Furthermore, the private sector, traditional health practitioners and non-governmental agencies provide healthcare services at all three levels of the healthcare system.

The reality regarding supplies of medicines in Nigeria is that those who are not trained and registered as pharmacists are actively involved in supplying pharmaceuticals, using unregistered premises. Rural and poor communities, which have no health facilities, receive medicines from patent stores and vendors in open market places.

The proposed drug distribution strategy restricts drug distribution to pharmacists, promotes rational drug use and strengthening of the inspectorate and monitoring units of the National Agency for Food and Drug Administration and Control (NAFDAC). The Mega Distribution Company Consensus Model (Figure 6) was proposed by the Government and PMG-MAN and has been agreed by the stakeholders. Technical support is required and logistics issues need to be addressed for this private-driven agency to commence operations. Moreover, adequate quantification of needs for each category of medicine at all levels of healthcare service is crucial to the efficient procurement of essential medicines.

2.5 Procurement of medicines and medical supplies

Procurement is a key challenge in the supply of medicines in Nigeria and, as in the case of distribution (see 2.6.2 below), procurement of medicines and medical supplies is fragmented and involves too many organizations. In the public sector, there is a national procurement policy and a dedicated procurement department has been created to cater for health related items. The idea is to involve all actors and pull together all procurement resources in order to enjoy pooled procurement benefits. To date, the central control of drug procurement has only started with respect to ARVs. Government funds are used to purchase first line ARVs while funds from development partners are used to purchase second and third line ARVs.

2.5.1 The Bureau of Public Procurement

The Bureau of Public Procurement (BPP) was established in 2007 by the Public Procurement Act to oversee all procurement processes in all public and government agencies. Procurements include procurement of goods, services and works. The objectives of the Bureau are harmonized with existing government policies and practices on public procurement and aim to ensure probity, accountability and transparency in the procurement process; the establishment of pricing standards and benchmarks; and the attainment of transparency, competitiveness, cost effectiveness and professionalism in the public sector procurement system.

The Bureau formulates the general policies and guidelines relating to public sector procurement for the approval of the National Council on Public Procurement (NCPP), publicizes and explains the provisions of the Public Procurement Act and supervises the implementation of established procurement policies. It has the power to enforce the monetary and prior review thresholds set by the Council for the application of the provisions of the Public Procurement Act by the procuring entities. BPP also has the power to review any procurement transaction to ensure compliance with the provisions of the Public Procurement Act and to debar any supplier, contractor or service provider who contravenes any provision of the Act. The establishment of the BPP will only impact on the local drug manufacturing sectors when some local firms obtain WHO prequalification status. However, if it adheres to its mandate, the Bureau will reduce the current chaotic and corrupt procurement practices.

2.5.2 Domestic preference policy

The Public Procurement Act 2007 made provision for a domestic preference policy. The BPP may grant a margin of preference in the evaluation of tenders when comparing bids from domestic companies with those from foreign firms or when comparing tenders from domestic suppliers offering goods manufactured locally with those offering goods manufactured abroad.

Where a procuring entity intends to allow domestic preferences, the bidding documents must clearly indicate that preference will be given to domestic suppliers and contractors and must also provide the information required to establish the eligibility of a bid for such preference. Margins of preference shall apply only to tenders under international competitive bidding. The BPP shall, by regulation, from time the time set the limits and compute the margins of preference and determine the contents of goods manufactured locally.

2.6 The supply chain and distribution of medicines

2.6.1 The supply chain

As of the end of 2009, 312,000 of an estimated 3 million adults and children in Nigeria living with HIV/AIDS received Antiretroviral Therapy (ART). The Government has set an ambitious goal of providing Antiretroviral (ARV) treatment to 694,000 people living with AIDS (PLWAs) by the end of 2011.

For this to be achieved, it is vital to strengthen the country's supply chain system for ARVs. Nigeria's HIV/AIDS supply chains – many of which include separate procurement, warehousing, and distribution systems – are owned and operated by various federal, state, non-governmental and faith-based stakeholders with oversight from the Federal Ministry of Health (FMoH) and the National Agency for the Control of AIDS (NACA).

To improve visibility and coordination across these disparate supply chains, the Supply Chain Management System (SCMS)[1] is working with FMoH, agencies funded through the President's Emergency Plan for AIDS Relief (PEPFAR) and implementing partners to strengthen quantification and procurement planning, logistics data collection and management, inventory control, storage and distribution, as well as supply chain coordination for HIV/AIDS commodities. In 2010, SCMS was scheduled to procure all first line ARV drugs and HIV test kits for PEPFAR partners in Nigeria, along with a broad array of laboratory equipment and supplies to support PEPFAR efforts and government goals in addressing the impact of HIV/AIDS in Nigeria.

SCMS is also responsible for coordinating procurement and supply management (PSM) activities among the various implementing partners, the Government of Nigeria, Global Fund Principal Recipients and the Clinton Foundation. Improved supply chain management will reduce the cost of distribution of medicines by local drug manufacturers to treatment centres. Since most of the drug manufacturers are based in Lagos and Ogun states, it will be cheaper and more convenient for them to supply to the Central Medical Store at Oshodi, Lagos State.

1 The Supply Chain Management System (SCMS) is implemented by the Partnership for Supply Chain Management of the US

2.6.2 Distribution of medicines

Distribution of medicines in Nigeria is chaotic and involves too many different bodies, organizations and stakeholders. Some major manufacturers contract private logistics organizations to distribute medicines and some international development partners even use the services of courier companies for delivery of medicines. In some cases, medicines expire before they reach the end users.

In the private sector, manufacturers and importers have their own distribution channels and can sell to wholesalers, retailers and hospitals. The result of this is that medicines and medical supplies are sold in unregistered and unlicensed premises and, in some cases, by non-pharmacists.

Moreover, it is generally believed that some 17 per cent of essential generic medicines as a whole are routinely faked and as much as 30 per cent of antimalarials in the Nigerian market (PMG-MAN). One way of tackling this problem would be through the introduction of Radio Frequency Identification Technology for Logistics and Tagging (see Box 1).

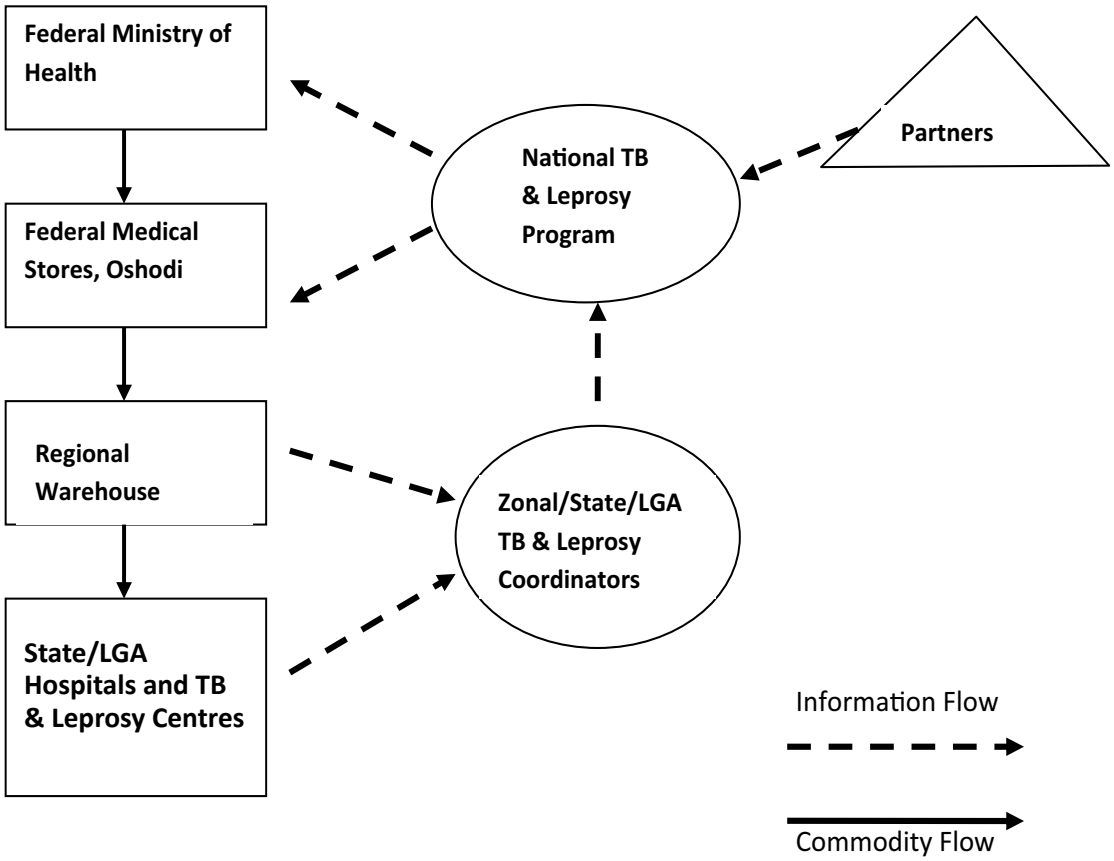
Box 1: Radio Frequency Identification Technology for Logistics and Tagging

In March 2010, the National Agency for Food and Drug Administration and Control (NAFDAC) launched a product verification initiative using Radio Frequency Identification (RFID) technology for logistics and tagging. This initiative is expected to reduce the counterfeiting of medicines. RFID tags can ensure that the integrity of the drug supply chain is more secure by tracking the product path as it moves through the supply chain from manufacturer to distributors, wholesalers, retailers, and finally to the consumers. When properly used, this innovation enables the consumer to verify the authenticity of the product by calling a free mobile phone number. It is encouraging for both the consumer and NAFDAC to see a reduction in the volume of fake medicines on the domestic market. Scanners will be used at all ports of entry to verify drug authenticity and it is planned to ensure that the scanners are affordable for all manufacturers, hospitals, pharmacists and other users.

In the public sector, medicine supplies are currently stocked and distributed through three different warehouses, the Central Medical Stores, the Federal Medical Stores and the State Medical Stores. In 2010, the National Health Logistics Committee was established to harmonize all logistics related to medicines supplied by the various development partners and Government. The Committee is expected to propose merging the existing three layers of warehousing of health commodities into one, the Central Medical Stores, with a branch in Oshodi and another in Abuja.

Figure 5 depicts the flow of information and TB/Leprosy medicines to the treatment centres, all of which are channelled through the Central Medical Stores at Oshodi in Lagos State to the regional warehouses. Based on information on the stock of medicines at the local government medical stores, the medicines are released to the treatment centres.

Figure 5: Flow of Information and TB/Leprosy Commodities



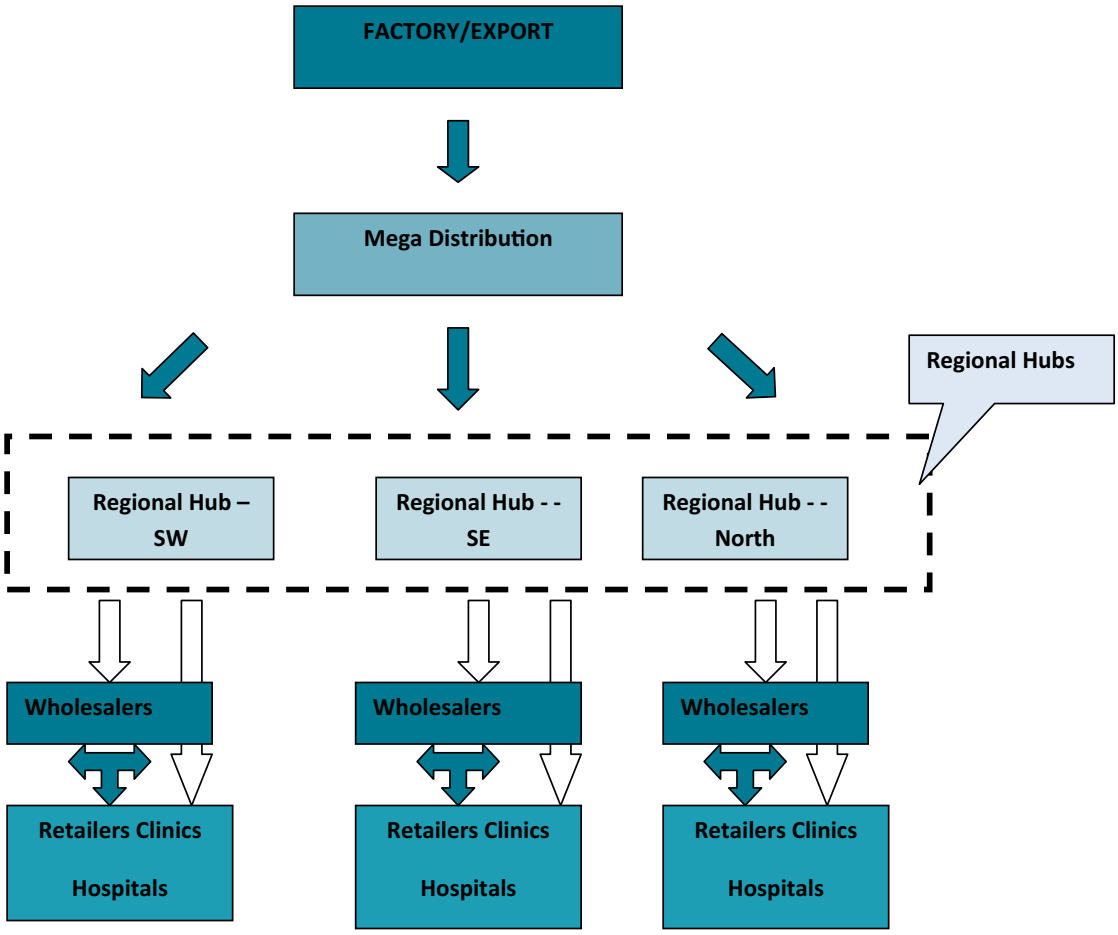
LGA = Local Government Area

Source: Federal Ministry of Health, Abuja, 2010.

In 2010, the National Health Logistics Committee was established to harmonize all logistics related to medicines supplied by the various development partners and Government. The Committee is expected to propose merging the existing three layers of warehousing of health commodities into one, the Central Medical Stores, with a branch in Oshodi and another in Abuja.

In order to improve the distribution of medicines within the public sector, the relevant stakeholders agreed on a Mega Distribution model in 2009. Figure 6 below shows the planned model for medicines and medical supplies in Nigeria, based on information from the National Drug Policy and discussions with the FMoH, the Pharmacists Council of Nigeria (PCN), NAFDAC, PMG-MAN and the WHO Country Office in Nigeria. The proposed Mega Distribution Company will be privately owned and managed as an independent corporate entity.

Figure 6: Mega Distribution Company Consensus Model



Source: Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN), 2009

The Government will be responsible for ensuring an appropriate business environment for the company and will call on its services to distribute health products which GoN has purchased. The proposed company will be responsible for the collection of health products from factory/export warehouses and distribution to regional warehouse hubs located in the South West, South East and Northern parts of the country. Wholesalers will then collect the health products from the regional hubs for distribution to retailers who are responsible for selling them to the end users in clinics, hospitals and institutions.

When, and if, the Mega Distribution Company is established, it will be able to collect health products from the Federal Medical Stores, Oshodi and distribute directly to health facilities throughout the country, including General Hospitals, Federal Medical Centres, Specialist Hospitals, Teaching Hospitals, primary healthcare centres, private clinics and pharmacies.

The proposed drug distribution strategy restricts drug distribution to pharmacists, promotes rational drug use and strengthening of the inspectorate and monitoring units of the National Agency for Food and Drug Administration and Control (NAFDAC). The Mega Distribution Company Consensus Model (Figure 6) was proposed by the Government and PMG-MAN and has been agreed by the stakeholders. Technical support is required and logistics issues need to be addressed for this private-driven agency to commence operations. Moreover, adequate quantification of needs for each category of medicine at all levels of healthcare service is crucial to the efficient procurement of essential medicines.

2.7 Prices of Medicines

Drug prices in Nigeria are set mostly by market forces, with government tariffs, taxes and distribution mark-ups accounting for a significant proportion of the final price. Prices vary between outlets, facilities and types of products, with generic drugs priced much higher than their equivalents in neighbouring countries.

A national survey on medicine prices was undertaken in 2006 by the Federal Ministry of Health in collaboration with the World Health Organization (WHO), the UK's Department for International Development (DFID), the European Union and Health Action International. The results of the survey are summarised in Box 2 below.

Box 2: Medicine Prices in Nigeria

- Patients pay between 2-64 times the international reference prices for medicines at various health facilities in both the private and public sectors
- Prices in the public sector were almost identical to those in the private pharmacies
- Private health clinics charge about 184 per cent more than the public health facilities and about 193 per cent more than private retail pharmacies
- Innovator brands cost between 2-7 times the lowest priced generic equivalents

The 2006 survey concluded that 90 per cent of Nigerians who live below the income level of US$ 2 per day, as well as Government workers who earn a minimum wage of US$ 1.4 per day, cannot afford medicines. This problem has been addressed in the revised National Drug Policy, which sets out to present acceptable determinants of medicine prices in all sectors, thereby making medicines more affordable. Furthermore, the establishment of the Bureau for Public Procurement will facilitate bulk purchase of medicines and other products, consequently reducing the cost of medicines in the market. However, a definite policy on medicine prices in Nigeria is still required to effectively address all issues related to this issue.

3. LOCAL PHARMACEUTICAL PRODUCTION

3.1 Introduction

The determining factor in the pharmaceutical business is the disease pattern and West Africa is no exception to this dictum. Malaria, HIV/AIDS, and tuberculosis, coupled with widespread malnutrition and poverty, represent a double burden of disease on the population. In addition, heart-related diseases are also on the increase. Consequently, over the counter medicines such as analgesics, antimalarials and multivitamins make up a large share of the market. Antiretroviral (ARV), artemisinin combination therapy (ACT), anti-TB and antimicrobial antidiarrhoeal agents are life saving for patients in Nigeria. Promotion of local production of these essential life saving medicines could make them more accessible for people with life threatening diseases provided that the price of such medicines is affordable.

Drug manufacturers in Nigeria are up against several constraints, including low capacity utilization, under capitalization, a weak financial base, high production costs as a result of the high cost of inputs, poor infrastructure, difficulty in meeting WHO prequalification criteria, low level or obsolete technology, high interest rates and unstable demand. The fluctuations in demand are a reflection of prevailing low purchasing power within the population and the fact that Government purchases of medicines are irregular and payments may be delayed.

Nonetheless, the pharmaceutical industry in Nigeria is vibrant, with over 120 pharmaceutical manufacturers and a predominantly indigenous ownership. The sector has a potential market value of between around US$ 600 million (BMI) and more than US$ 2 billion annually (PMG-MAN) and employs about 500,000 persons in the manufacturing and distribution chain. The vast majority of jobs are however attributed to the distribution chain. Some 60 per cent of pharmaceutical production in the Economic Community of West African States (ECOWAS) is domiciled in Nigeria. The regulatory environment is improving due to the enforcement activities of the National Agency for Food and Drug Administration and Control (NAFDAC) although drug distribution is still a challenge.

Capacity utilization of local manufacturing facilities is running at about 40 per cent and there is adequate capacity for production of certain categories of medicines to meet national demand and to export to ECOWAS countries. The Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria, with the acronym PMG-MAN, is the professional organization for drug manufacturers in Nigeria.

Currently, some local drug manufacturers are upgrading their operations with the aim of obtaining World Health Organization (WHO) prequalification status which would enable them to take part in international tenders. If successful, this will be another contributing factor to an increase in local production and has the potential to make these medicines available closer to where they are needed.

3.2 Structural characteristics

According to the Pharmacists Council of Nigeria (PCN), there were 128 registered drug manufacturers, 1,534 retail pharmacies, 724 drug distributors and 292 drug importers in Nigeria in 2010. Nigeria has a total of 14,607 public and 9,034 private healthcare facilities (National Bureau of Statistics, 2006a). However, it has been estimated that there are over 10,000 unregistered patent and proprietary medicine stores, which are thought to sell over the counter (OTC) products only. Most such stores are located in villages and poor communities throughout the country, in areas where fully fledged pharmacies do not exist.

3.3 The pharmaceutical value chain

A value chain describes the full range/sequence of discrete, value-added activities needed to bring a specific product/service from its conception through the different stages of production to its use and final disposal after use (UNIDO, 2004).

3.3.1 Supply of inputs

All active pharmaceutical ingredients (APIs) used in Nigeria are imported, mainly from India and China. Companies need to make careful forward planning for the import of APIs because of lengthy delays (three months or more) at the seaport due to clearance, customs and NAFDAC formalities.

According to PMG-MAN, pharmaceutical grade starch is currently imported primarily from China and there are local companies which produce industrial grade starch. The National Institute for Pharmaceutical Research and Development (NIPRD) has carried out research and development into pharmaceutical grade starch since it would be very advantageous to local drug manufacturers if starch could be processed locally to produce pharmaceutical grade starch, pre-gelatinised starch used as pharmaceutical binder, and dextrose monohydrate marketed as glucose powder (nutraceuticals), which is a major ingredient in intravenous infusions.

In 2009, China and India introduced penalties, including life imprisonment (India) and the death penalty (China) for companies which export substandard finished products to Nigeria and other countries. At a recent international conference in Morocco on pharmacovigilance, it was agreed to extend the law to cover APIs and WHO agreed in principle to commence the mandatory processes for the approval of the inclusion of API manufacturers in the WHO prequalification scheme.

In most cases, both primary and secondary packaging materials are obtained locally. In addition, about 25 per cent of excipients are locally sourced.

Most of the machinery and virtually all the quality control analytical equipment are imported, mainly from Asia and Europe respectively. Some of the drug manufacturers fabricate a few spare parts but most are imported. Some companies, which are using similar machines supplied by the same foreign companies in India and in Europe, also join together to contract expatriate engineers and to organize workshops on machine maintenance.

Infrastructure and access to utilities is generally very poor for the manufacturing sector. For example, companies are obliged to install generators to ensure their supply of electricity. Furthermore, bore holes are constructed and water treatment facilities installed in order to obtain a supply of good quality water for production purposes. PMG-MAN has estimated that these additional utility costs range between 25 per cent and 40 per cent of production costs.

Most of those employed in the local pharmaceutical manufacturing sector are semi-skilled workers who acquire their skills on the job and in in-house workshops organized by the industry. In many cases, expatriates are engaged to train local staff for limited periods of time in specific technical skills but most of the staff engaged by the local drug manufacturers at both management and technical levels are Nigerians.

3.3.2 Production of pharmaceuticals

The local pharmaceutical manufacturing industry is currently able to meet 25 per cent of local demand. Nigerian manufacturers produce liquid preparations, tablets, capsules, ointments, lotions, creams and ophthalmic preparations. The local pharmaceutical industries are able to meet domestic demand for some classes of medicines in the proportions listed in Table 13. The remaining 75 per cent of the market is increasingly dominated by imports from Asian companies.

Generally, the production flow scheme is in accordance with Good Manufacturing Practice. Production processes are step-by-step, mixed manual and automated with the degree of automation varying between around 30 per cent and 80 per cent. Although nearly all of the 15 companies interviewed in the course of this report indicated that they planned to become fully automated, none had yet achieved this goal although some of them had reached the 80 per cent stage.

The current installed capacity in the industry, as verified by various Government Committees and in this report is shown in Table 13 below and the average capacity utilization is 40 per cent. Although this represents a substantial volume of under utilized capacity, it also means that ample spare capacity is available - without extensive new capital investment - if manufacturers can become more competitive with imported products.

3.4 Plant-level assessments

For the purposes of this report, an appropriate questionnaire was developed (see Annex 5) and distributed to selected local drug manufacturers. After discussions with PMG-MAN, a sample of 15 manufacturers was selected to participate and their responses to the questionnaire are reproduced in Annex 3. Personal interviews were also carried out and the list of those interviewed is shown in Annex 2.

The products manufactured by these companies are all essential medicines, including antimalarial, antiretroviral, antibacterial, anticough, analgesic/antipyretic, vitamins, haematinics, antacids, medicines, etc. Liquid, capsule, tablet and topical formulations are commonly produced by the companies covered in this report.

The ownership structure was predominantly indigenous (i.e. eight out of the 15 companies were 100% owned by Nigerians). Four of the companies had foreign majority shareholders while the remaining three were jointly owned by Nigerians and foreigners. The annual turnover of the profiled companies ranges between 380 million Naira (US$ 2.53 million) and 5.4 billion Naira (US$ 360 million).

3.5 Summary of the SWOT analysis

An overall assessment of the pharmaceutical sector in Nigeria using Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis is indicated below.

Strengths

- 60 per cent of pharmaceutical production in ECOWAS countries is domiciled in Nigeria (although current capacity utilization is only about 40 per cent)
- There is abundant under-utilized manufacturing capacity that can be applied to manufacture new products upon demand
- The attainment of WHO cGMP and prequalification status by some companies (currently in progress) will enable them to participate in international tenders for supplies of antiretrovirals, antimalarials and anti-TB medicines and will thus represent a very large expansion of potential demand
- Technical skills, trained manpower and basic manufacturing infrastructure already exist, with about 120 local drug manufacturing companies. Nigeria thus has the potential to become a leading manufacturer and distributor of essential medicines in sub-Saharan Africa

Weaknesses

- Poor infrastructure (power, water, transportation) which increases the cost of local medicine manufacture and distribution and constrains growth
- No Nigerian medicine manufacturer has yet attained WHO cGMP or WHO prequalification status. Consequently, local firms cannot participate in international tenders for pharmaceutical supplies and their ability to participate in the international pharmaceutical trade is limited
- Access to affordable funding for local manufacturers is hampered by high bank interest rates. Consequently, funds required for working capital and upgrading of facilities are limited

Opportunities

- The large market size, strong demand and the need for improved management of infectious diseases (especially HIV/AIDS, malaria, TB, and "neglected childhood diseases")
- Increased research and development efforts at the National Institute for Pharmaceutical Research and Development and national universities can lead to the emergence of new therapeutic agents, nutraceuticals and phytomedicines from Nigeria's abundant indigenous biodiversity and traditional medicines
- Positive economic growth in recent years and macroeconomic stability are helping to reduce poverty and increase purchasing power
- 60 per cent of drug manufacturing in the ECOWAS subregion takes place in Nigeria, underlining the huge subregional market
- The increasingly visible and active National Agency for Food and Drug Administration and Control (NAFDAC) and, in particular, its aggressive campaign against substandard health products have shown a positive impact on reducing the counterfeit drugs trade
- Regional regulatory harmonization (in progress) through the West African Drug Regulatory Authorities Network (WADRAN) to promote trade within the West African subregion
- Trade incentives introduced by ECOWAS for pharmaceuticals within West Africa are helping to promote movement of pharmaceuticals within the subregion
- The establishment of the West African Pharmaceutical Manufacturers Association (WAPMA) which aims to strengthen local medicine production
- Government policy aiming to achieve local production of 70 per cent of essential medicines
- Government ban on imports of some essential medicines for which there is adequate domestic capacity and technical skills
- Establishment of the National Health Insurance Scheme (NHIS) to provide universal healthcare coverage by 2015 will provide funds for the required essential medicines

Threats

- The unacceptable level of poverty - very weak purchasing power threatens the scope for marketing health products and encourages the proliferation of informal open markets. This informal market for medicines exists throughout Nigeria and in villages and rural communities it is the only means of access to medicines. The cost of medicines sold in the informal market is significantly lower than that of those sold at registered pharmacy stores

- Failure to remedy the dysfunctional distribution system; a combination of political will, capacity building and technical/logistics support is needed if the distribution system for health products is to be improved

- The stigma of substandard health products affects the international marketing of medicines produced in Nigeria. However, the activities of WADRAN and WAPMA will promote marketing of health products manufactured by members of the PMG-MAN within the subregion

- Drug price control policy has not yet been articulated by the Federal Government. The current prices of health products in the market are high and most Nigerians cannot afford them

- Corruption is widespread in most transactions. This practice, if not adequately addressed, may eventually discourage local manufacturing of health products

In spite of the weaknesses and threats identified in the SWOT analysis, the pharmaceutical industry sector has grown between 10 per cent and 15 per cent in the last five years (PMG-MAN, 2010).

The SWOT analysis of the individual companies undertaken through interviews revealed that most of them are strong in their specific brands, regular human capacity training workshops and distribution networks. On the other hand, they see problems with regard to access to funds at reasonable interest rates for factory improvement and WHO prequalification requirements.

The companies have certain opportunities, including a potentially huge subregional market (ECOWAS) and global initiatives supporting HIV/AIDS, TB and malaria. However, local drug manufacturers are threatened by the low purchasing power of consumers, cheaper competing imported medicines and counterfeits of their branded products.

All the manufacturing companies suffer from poor infrastructure and the high cost of utilities (power, water, etc.). However, given the relative political stability, economic growth and favourable policies for local drug manufacturers, it is nonetheless still profitable to invest in the pharmaceutical industry in Nigeria (PMG-MAN, 2009).

3.6 Installed capacity and current output

The current installed capacity in the industry, as verified by various Government Committees and in the course of this report, is shown in Table 13 below. The average capacity utilization is 40 per cent.

Table 13: Installed Capacity of Drug Manufacturers in Nigeria

	Products	*Installed capacity/year*
1	***Analgesics***	
	Tablets	40 billion
	Syrup/suspension	70 million litres
	Ointments/Balms	700 million tubes
2	***Antimalarials***	
	Tablets	8 billion
	Capsules	5 billion
	Syrups	50 million litres
3	***Antibiotics***	
	Tablets	20 billion
	Capsules	20 billion
	Syrups	40 million litres
4	***Antiretrovirals***	
	Tablets	20 billion
	Syrups	30 million litres
5	***Vitamins***	
	Tablets	50 billion
	Capsules	40 billion
	Syrups	80 million litres
6	***Antitussive syrups***	45 million litres
7	***Infusions***	500 million litres
8	***Antacids***	
	Tablets	30 billion
	Syrups	50 million litres
9	***Antiseptics / Disinfectants***	60 million litres
10	***Injectables***	400 million vials

Source: PMG-MAN, Lagos, 2010.

The low capacity utilization in the pharmaceutical manufacturing sector is attributed mainly to the current lack of competitiveness with imported products and to unpredictable demand for the products. A major challenge faced by local producers is the cost of importing all their active pharmaceutical ingredients and virtually all their pharmaceutical excipients. The burden is then multiplied by the fact that local manufacturers must pay Value Added Tax (VAT) on the imported raw materials whereas there is no VAT on imported finished medicines. Furthermore, some foreign pharmaceutical manufacturers, such as those in India, produce both pharmaceutical raw materials and the finished products. Such companies have an added advantage when they export both the raw materials and medicines to Nigeria through pricing that will favour their finished products.

Surveys conducted by the Federal Ministry of Health in 2008 on the output of medicines locally manufactured in Nigeria are summarized in Box 3.

Box 3 - Volumes of some medicines manufactured locally in Nigeria

1. Out of the 49 local drug manufacturers reviewed, 15 were found to be manufacturing ampicillin/cloxacillin capsules producing a total of some 1.216 billion and three companies manufactured 7.882 million grams of the powder.
2. Two companies manufactured 180 million amoxicillin capsules and five manufactured 187.6 million grams of the powder.
3. Four companies produced 193.6 million ampicillin capsules and four manufactured 367.2 million grams of the powder for suspension.
4. Nine companies produced 2.4 billion ascorbic acid tablets and eight produced 902.8 million litres of ascorbic acid syrup.
5. Two companies manufactured both chlorphenamine tablets and syrup.
6. Two companies manufactured a total of 4.961 million litres of glucose infusion 5 per cent, 10 per cent, 5 per cent + 0.9 per cent sodium chloride, 4.3 per cent and two companies manufactured 1.33 million litres of sodium chloride.

3.7 The leading local drug manufacturers

The total revenue generated by the 20 leading Nigerian pharmaceutical manufacturers from local production of some essential medicines is shown in Table 14

Table 14: The 20 leading Nigerian Pharmaceutical Manufacturers by Total Revenue (2008)

Rank	*Company*	*Estimated annual revenue (US$ million)*
1	GlaxoSmithKline Nigeria	80
2	May & Baker Nigeria Plc	40
3	Fidson Healthcare Plc	40
4	Emzor Pharmaceutical Industries Ltd	40
5	Juhel Nigeria Ltd	40
6	Evans Medical Plc	30
7	Swiss Pharma Nigeria Limited (SWIPHA)	25
8	Nigerian-German Chemicals Plc (NGC Plc)	25
9	Ranbaxy Nigeria Limited	25
10	Vitabiotics (Nig) Ltd	20
11	Neimeth International Pharmaceuticals Plc	15
12	Afrab-Chem Limited	15
13	Tuyil Pharmaceutical	15
14	Pharma-Deko Plc	15
15	Bentos Pharmaceutical Products Ltd	15
16	Mopson Pharmaceutical Industries Ltd	15
17	Morison Industries Plc	15

Rank	*Company*	*Estimated annual revenue (US$ million)*
18	Daily-Need Industries Ltd	15
19	SKG-Pharma Ltd	10
20	Drugfield Pharmaceuticals Ltd	10
	Total Revenue	505

Source: PMG-MAN

Local drug manufacturers are not currently in a position to participate in international tenders for medicines against the three pandemics that require WHO prequalification. This is a major constraint on the local supply of medicines, especially ARVs, antimalarials and anti-TB agents. In addition, these are the main medicines attracting substantial funding from international development partners. Some six local drug manufacturers are currently modifying their production processes with the aim of complying with the WHO prequalification requirements. If they are successful and able to compete against imports, the volume of local production of pharmaceuticals and sales will increase substantially.

Moreover, a 2008 survey conducted by the FMoH found that average annual local production levels in solid dosage forms increased from about 15 per cent to 40 per cent following the introduction of an import ban on some essential medicines (see Table 15).

Table 15: Average Annual National Production of Health Products on the Import Prohibition List

	Tablets	*Syrups (Litres)*
Paracetamol	76,862,821,591	2,258,474,114
Co-trimoxazole	1,446,797,876	193,796,390
Chloroquine	336,038,307	1,325,236,000
Metronidazole	1,295,122,945	1,400,000,000
Ferrous gluconate	666,855,000	
Ferrous sulfate	1,272,000,000	
Folic acid	1,316,508,717	
Vitamin B Complex	2,805,506,155	
Multivitamin	1,673,301,741	922,754,584
Acetyl salicylic acid	242,550,000	
Mag. Trisilicate	620,337,000	13,955,983
Piperazine	200,000,000	6,667
Levamisole	50,000,777	
Clotrimazole cream	100,068,221	
Ampicillin/cloxacillin cap	1,184,586,740	8,235,000
Penicillin/gentamicin/oint	251,097,381	
Pyrantel pamoate	1,692,607	750

Source: FMoH Survey, 2008

3.8 Revenue and the capital market

The total annual revenue of the top 20 Nigerian pharmaceutical manufacturers is estimated at US$ 505 million (PMG-MAN, 2008). Ten of these companies are listed on the floor of the Lagos Stock Exchange (Table 16).

Table 16: Pharmaceutical Companies listed on the Stock Exchange in Nigeria

	Pharmaceutical company
1	GlaxoSmithKline Nigeria
2	May & Baker Nigeria Plc
3	Fidson Healthcare Plc
4	Nigerian-German Chemicals Plc
5	Evans Medical Plc
6	Neimeth International Pharmaceuticals Plc
7	Pharma-Deko Plc
8	Morison Industries Plc
9	PZ Cussons Nigeria Plc
10	Boots Company (Nig.) Plc (BCN Plc)

3.9 Market shares

The market share of the various therapeutic classes of medicines locally produced in Nigeria are indicated in Table 17. The class of analgesics/antirheumatics/antipyretics has the largest share due to their affordability and availability in both urban and rural communities, as well as widespread use and misuse of these products for a wide range of symptoms.

Table 17: Estimated Market Share of Local Manufacturers by Therapeutic Class

	Name	***Market share***
1.	Analgesics/antirheumatic/antipyretics	25%
2.	Antibiotics + antibacterials	15%
3.	Multivitamins + haematinics	15%
4.	Antimalarial medicines	14%
5.	Antihypertensives	8%
6.	Cough anad cold preparations	5%
7.	Antiretroviral medicines	6%
8.	External/topical preparations	5%
9.	AntiTB medicines	4%
10.	Others	3%
	Total	***100%***

Some drug manufacturers have diversified into other products, including bottled water, packaged foods, nutraceuticals, and cosmetics using new industrial subsidiaries established for such purposes.

3.10 Local production of medicines for malaria, tuberculosis, and HIV/AIDS

3.10.1 Malaria

The list of local pharmaceutical manufacturers producing medicines for the treatment of acute attacks of malaria is shown in Table 18 below. Their ability to continue producing ACTs will depend on their success in qualifying for participation in international tenders, amongst others for the AMFm.

Table 18: Local Artemisinin Combination Therapy (ACT) Manufacturers

Company	***Antimalarial (ACTs)***
Bond Chemical Industries Ltd	Artesunate + Amodiaquine (Efonrex Tablets)
May & Baker Nigeria Plc	Artesunate 100Mg, Amodiaquine Hcl 400Mg (Malact)
	Artemether+Lumefantrine (A rtelum) Tablets
Swipha Nigeria Ltd	Artesunate + Lumefantrine (Farenax) Tablets
	Artesunate 200Mg, Amodiaquine Hcl 780Mg (Dart) Tablets
	Artesunate 50Mg, Amodiaquine Hcl 260Mg (Dart) Tablets For Children)
Emzor Pharmaceutical Industries Ltd.	Artesunate 100Mg + Amodiaquine 400Mg (Diasunate) Tablets
	Artemether+ Lumefantrine (Locmal) Tablets
Fidson Healthcare Plc	Artesunate 100Mg + Amodiaquine 400Mg (Malmed) Tablets
	Artemether+Lumefantrine (A rthemed) Tablets
Ecomed Pharma Ltd	Artesunate 100Mg + Amodiaquine 400Mg (Actpro) Tablets
	Artemether+ Lumefantrine (Actpro Al) Tablets
Evans Medical Plc	Artesunate 100Mg + Amodiaquine 400Mg (Mednovas Kit)
	Artemether+ Lumefantrine (Artemef) Tablets
Therapeutic Laboratories (Nig.) Limited	Artesunate 50Mg + Amodiaquine 200Mg (Quinamet) Tablets
	Artemether+Lumefantrine (Lu mether) Tablets
	Artemether 10Mg + Lumefantrine 60Mg (Lumether Paediatric D ispersible Tablets)
Afrab-Chem Limited	Artemether+ Lumefantrine Suspension
SKG-Pharma Ltd	Artesunate 100Mg, Amodiaquine 400Mg Tablets
	Artemether+ Lu mefantrine Tablets

3.10.2 Tuberculosis

Nigeria has the world's fourth highest incidence of tuberculosis (TB), with nearly 374,000 estimated new cases annually, and the disease is becoming an ever greater public health

burden as the incidence of HIV/AIDS rises. WHO has estimated that some 27 per cent of Nigeria's TB patients are HIV positive. Despite this prevalence, most of Nigeria's anti-TB and leprosy medicines are funded by international development partners and consequently they have not attracted the attention of local manufacturers, who would not be able to market these drugs.

3.10.3 HIV/AIDS

Local pharmaceutical manufacturers of medicines for the management of HIV and AIDS are shown in Table 19 below.

Table 19: Manufacturers of Antiretrovirals (ARVs) in Nigeria

Company	*Antiretrovirals (ARVs)*
Ranbaxy Nigeria Limited	Avolam Liquid (Lamivudine 50Mg)
	Azido Liquid (Zidovudine 50Mg)
	Nevran Liquid (Nevirapine 50Mg)
Fidson Healthcare Plc	Virex Lzn (Lamivudine+Zidovudine+Nevirapine Tablets)
	Virex Lz (Lamivudine + Zidovudine Tablets)
	Virex L (Lamivudine Syrup)
	Virex Z (Zidovudine Syrup)
	Virex N (Nevirapine Suspension)
Archy Pharmaceuticals Ltd	Archivir (Lamivudine 50Mg + Stavudine + Nevirapine) Tablets
May & Baker Nigeria Plc	Lamar (La mivudine) Tablets
	Stavar (St avudine) Tablets
	Nevipar (Nevirapine) Tablets
Gemini Pharmaceuticals Nigeria Limited	Viramune (Ne virapine) Tablets
Emzor Pharmaceutical Industries Ltd	Nevirapine Syrup
	Zidovudine+Lamivudine Tablets
Drugfield Pharmaceuticals Limited	Fluconazol (Flucamed Capsules 200Mg)
	Antirovir Capsules (Lamivudine + Zidovudine)
Swipha Nigeria Ltd	Virazid (Zidovudine 100Mg) Tablets
Evans Medical Plc	Arved Tablets (Lamivudine + Zidovudine)
	Arved – N Tablets (Lamivudine + Zidovudine + Nevirapine)
	Lavudine – S 30/40 Tablets (Lamivudine + Stavudine)
	Lavudine Snp – 30/40 Tablets (Lamivudine + Stavudine + Nevirapine)
Vitabiotics (Nig) Ltd	Efavirenz Tablets

3.10.4 Neglected Tropical Diseases (NTDs)

The local pharmaceutical industry has a comparative advantage in providing remedies for neglected tropical diseases (NTDs). For example, the National Institute for Pharmaceutical

Research and Development (NIPRD) developed a phytomedicine called Niprisan from four botanical species indigenous to Nigeria for the management of sickle cell anaemia. Niprisan was subsequently licensed to an American company, Xechem Inc., which gave it a generic name of Nicosan. Nicosan is now manufactured from 100% local active pharmaceutical ingredients (APIs) by Xechem Nigeria Limited, which is located in the Science and Technology Complex, Sheida, Abuja.

This development shows that there is potential for new phytomedicines in Nigeria and NIPRD is developing more such medicines against malaria, fungal infections and HIV/AIDS. Furthermore, many researchers in Nigerian universities are actively involved in phytochemical screening and pharmacological/toxicological evaluation of various extracts of medicinal plants.

3.11 Export of locally produced Pharmaceuticals from Nigeria to other ECOWAS countries

Most of the medicines produced locally are consumed domestically. According to PMG-MAN, Nigeria is responsible for about 60 per cent of medicines produced in the ECOWAS subregion, which has an estimated population of 280 million and a market size of US$ 3.5 billion for health products. Table 20 lists Nigerian pharmaceutical companies which export their manufactured medicines to other ECOWAS countries.

Table 20: Nigerian Pharmaceutical Manufacturers exporting to ECOWAS

- PZ Cussons Plc
- May & Baker Nigeria Plc
- Fidson Healthcare Plc
- Evans Medical Plc
- Neimeth International Pharmaceuticals
- GlaxoSmithKline Nigeria
- Mopson Pharmaceutical Industries Ltd
- Emzor Pharmaceutical Industries Ltd
- Drugfield Pharmaceuticals Ltd

The geographical distribution of pharmaceutical manufacturers in the ECOWAS region (Botwe and Okelola, 2009) is shown in Table 21 below:

Table 21: Geographical Distribution of Pharmaceutical Manufacturers in the ECOWAS Region

	Country	*Number of Manufacturers*	*Remarks*
1	Benin	1	Francophone
2	Burkina Faso	-	Francophone
3	Cape Verde	1	Lusophone
4	Cote d'Ivoire	2	Francophone
5	Gambia	-	Anglophone
6	Ghana	36	Anglophone
7	Guinea	1	Francophone
8	Guinea-Bissau	-	Lusophone
9	Liberia	-	Anglophone

	Country	*Number of Manufacturers*	*Remarks*
10	Mali	1	Francophone
11	Niger	-	Francophone
12	Nigeria	120	Anglophone
13	Senegal	2	Anglophone
14	Sierra Leone	-	Anglophone
15	Togo	2	Francophone
Total 166 - (Anglophone = 156, Francophone = 9, Lusophone = 1)			

3.12 Nigerian Good Manufacturing Practices

In 2009, WHO, in collaboration with NAFDAC, developed Nigerian Good Manufacturing Practices (NGMP). Subsequently, training workshops were organised by WHO for both PMG-MAN and NAFDAC on this subject. The appropriate application of these principles will enhance local manufacturing standards and improve the quality of locally produced medicines.

4. THE BUSINESS ENVIRONMENT FOR PHARMACEUTICAL SECTOR PERFORMANCE AND DEVELOPMENT

This chapter outlines the main elements of the National Drug Policy (NDP) and other relevant government policies that show the political will of the Government of Nigeria to promote local production of essential medicines. As a clear demonstration of the Government's commitment, specific incentives have been approved and implemented, including banning the importation of essential medicines which are produced in adequate volume locally in a move designed to stimulate local production. A survey of the cost of local equivalents of banned medicines showed a range of between 0.2 and 1.5 times international market prices.

4.1 Policy framework

Nigeria's approach to addressing the Millennium Development Goals (MDGs) adopted by the United Nations in September 2000 is expressed in the National Economic Empowerment Development Strategy (NEEDS).

NEEDS focuses on four key areas:

- Reforming government and institutions to improve service delivery to poor people, eliminating waste, and fighting corruption
- Expanding the private sector by reducing the influence of government in the economy and accelerating privatization, deregulation and liberalization. A particular focus is on economic infrastructure, including transport and electricity
- Implementing a Social Charter to improve people's access to health, education, welfare, employment, empowerment, security and participation. HIV/AIDS is acknowledged as a major threat to the economy and not 'just' a social problem
- Emphasising that NEEDS is not 'business as usual' but rather gives special attention to privatisation, the fight against corruption, freedom of information, and enhancing the role of civil society.

In 1995, the Nigerian Investment Promotion Commission (NIPC) was established under the NIPC Act. The Commission is a Federal Government agency established to encourage, promote and coordinate investments in Nigeria. It provides services including the granting of business entry permits, licences, authorisations and incentives.

4.2 Support to business

4.2.1 Investment and tax incentives

In 2007, NIPC published an investment incentives brochure outlining various incentives approved by Government to stimulate private sector investment from within and outside the country. While some of these are applicable to all economic sectors, others are limited to specific sectors. The nature and application of these incentives has been considerably simpli-

fied. For example, the tariff structure for pharmaceuticals has been designed to discourage imports and stimulate local drug production.

NIPC is responsible for encouraging, promoting and coordinating investments in Nigeria. The agency provides services for the granting of business entry permits, licences, authorisations and incentives.

Incentives with implications for the pharmaceutical sector include:

- The Companies Income Tax Act has been amended to encourage potential and existing investors and entrepreneurs. The current rate of tax on companies in all sectors, except petroleum, is 30 per cent

- Pioneer status is a tax holiday granted to eligible industries (including the formulation and manufacture of pharmaceuticals) anywhere in the Federation and provides for a seven year tax holiday for industries located in economically disadvantaged Local Government Areas of the Federation. To qualify, a joint venture company or a wholly foreign owned company must have incurred capital expenditure of not less than 5 million Naira (about US$ 41,600) whilst a qualified indigenous company should spend no less than 150,000 Naira (about US$ 1,200)

- Up to 120 per cent of expenses on research and development (R&D) are tax deductible, provided that such R&D is carried out in Nigeria and is connected with the business from which the income or profit is derived

Other incentives include:

- Industrial establishments that have set up in-plant training facilities enjoy a 2 per cent tax concession for a period of five years

- Industries that provide access roads, pipe borne water and electricity can deduct 20 per cent of these costs from their taxes

- Industries with a high labour : capital ratio are entitled to tax concessions

- A re-investment incentive in the form of a generalised allowance for capital expenditure incurred is granted to companies for the expansion of production capacity, modernisation of production facilities and diversification into related products

- A tax credit of 20 per cent is granted for five years to industries that attain a minimum level of local raw material sourcing and utilization. The minimum levels are (by sector) Agro-allied 70 per cent, Engineering 60 per cent, Chemicals 60 per cent, and Petrochemicals 70 per cent

- Manufacturing companies with turnover of less than 1 million Naira (about US$ 8,000) are taxed at a low rate of 20 per cent for the first five years of operation

- Dividends from companies in the manufacturing sector with turnover of less than 1 million Naira (about US$ 8,000) are tax free for the first five years of operation

4.2.2 The Small and Medium Enterprises Development Agency of Nigeria (SMEDAN)

The Small and Medium Enterprises Development Agency of Nigeria (SMEDAN) is a government body established by the SMEDAN Act of 2003 to promote the development of the Small, Micro and Medium Enterprises (SMME) sector of the economy. Its mission statement includes commitments to facilitate the access of micro, small and medium-sized enterprises/investors to resources required for their development; to trigger the development of Nigeria's SMMEs in a structured and efficient manner; and to be one of the most positive channels to combat poverty. Further information is available at: www.smedan.gov.ng

According to PMG-MAN, about 50 per cent of its members qualify as SMEs, using a criterion of company annual turnover of less than 2 billion Naira. They are thus able to benefit from the support services offered by SMEDAN which can be summarized as follows:

- Stimulating, monitoring and coordinating the development of the SME sector
- Initiating and articulating policy ideas aimed at the growth and development of micro, small and medium-sized enterprises; promoting and facilitating development programmes, instruments and support services to accelerate the development and modernisation of SME operations
- Serving as a vanguard for rural industrialization, poverty reduction, job creation and enhancing sustainable livelihoods
- Linking SMEs to internal and external sources of finance, appropriate technology, and technical skills, as well as to large enterprises
- Promoting information and providing access to industrial infrastructure such as factory layouts, incubators, industrial parks
- Intermediating between SMEs and the Government; SMEDAN is the voice of the SMEs
- Working in concert with other institutions in both the public and private sectors to create a good enabling environment for businesses in general and for SME activities in particular

4.3 National Health Policy

The Federal Ministry of Health (FMoH) is responsible for implementing the National Health Policy (NHP). In 2004, a Health Sector Reform Programme was launched by the Ministry, outlining key strategies and a plan of action (2004-2007). The overall objective was to significantly improve the health status of Nigerians and reverse the vicious cycle of poverty, ill-health and underdevelopment which is underlined by the fact that Nigeria ranks 187 out of the 191 member states of the World Health Organization, based on its health indicators.

Nigeria's health policy also reflects the Health Strategy of the New Partnership for Africa's Development (NEPAD), the MDGs and the New Economic Empowerment Development Strategy (NEEDS) of Nigeria.

The NHP 2004 attempted to address the inadequacies of the health sector by identifying and recommending improvements in seven priority areas:

- Increased funding of the health system
- Expansion of information communication technologies in the Department of Food and Drug Services, Federal Ministry of Health
- Promotion of local production of essential medicines
- Improved consumer awareness
- Promotion of effective partnership collaboration and coordination
- Revitalisation of the primary health care (PHC) system
- Strengthening of regulatory mechanisms

The framework and plan of action for local production of essential medicines are outlined in the Health Sector Reform Programme, 2004-2007 (FMoH, 2004). Among others, this includes the promotion of pharmaceutical research and development of raw materials for production, compounding and formulation of pharmaceutical products. A new tariff structure was also approved in 2005 and is being implemented by the Federal Ministry of Finance. The Government has also made a commitment to implement fully the provisions of the revised National Drug Policy (see 4.4 below). A Presidential Task Force on the Local Production of Drugs was established by the former President of Nigeria, President Olusegun Obasanjo and is still functional. Box 4 summarizes the Government's rationale in promoting the local production of medicines.

Box 4: Reasons for Promoting the Local Manufacture of Medicines

- To attain self sufficiency in local production of essential medicines
- Access to medicines
- Creation of employment opportunities
- Contribution to internal revenue for the government
- Economic empowerment of citizens
- Contribution to poverty reduction
- Generation of foreign exchange
- Achieve the 7-point agenda of the Government

4.3.1 The National Health Act

No National Health Act has yet been passed although a draft health law is currently being prepared. When enacted, it will provide legal backing to the health policy, define the national health system and stipulate health-related actions at each level of government. The National Health Act will also provide the legal instruments that govern and regulate health and health-related activities in Nigeria, including the pharmaceutical sector.

4.3.2 The National Health Insurance System (NHIS)

In a related move, the government has attempted to address the country's healthcare problems with the introduction of the National Health Insurance System (NHIS). The scheme was officially launched in June 2005, with a presidential directive that there should be universal coverage by 2015. The aim is to oblige all public and private sector employees to contribute 15 per cent of their salary (5 per cent is provided by employees and the remainder by employers) towards the Health Maintenance Organization (HMO), which will arrange for the necessary healthcare.

The government has so far committed a total sum of 26 billion Naira for the scheme, with 14 billion Naira estimated to have already been released. Official sources say that, as of August 2007, 1.2 million people had benefited from the scheme. However, significant obstacles remain – most notably funding – before the NHIS can be extended to the informal sector. At present, coverage is restricted to the contributor, the spouse and a maximum of four dependants, a relatively small number in view of Nigeria's population profile.

4.4 National Drug Policy

Nigeria's first National Drug Policy (NDP) was launched in 1990 with the main objective of improving drug availability, supply and distribution. This objective faces substantial challenges. The first obstacle to a smooth functioning medicine supply chain is the existing inefficient system of drug administration and control. Added to this, there is the problem of inadequate funding of drug supplies and drug control activities and high dependence on imports of finished drug products, pharmaceutical raw materials, reagents and equipment.

Procurement practices are deemed to be sub-optimal, often resulting in poor selection of successful bids. This problem can be partially explained by the substantial number of unqualified staff involved in the procurement, distribution and sale of medicines. The actual suppliers of medicines to public care institutions also often perform poorly and, finally, there is a lack of political will to provide the safe, efficacious and good quality medicines needed to meet the health needs of the population.

Nonetheless, there have been some clear developments in the implementation of the NDP, including the adoption and subsequent publication of an Essential Drug List (EDL), a National Drug Formulary (NDF), and the establishment of the National Agency for Food and Drug Administration and Control (NAFDAC) in 1993, with the introduction of drug registration procedures.

Furthermore, the National Drug Policy aims at reaching 70 per cent local production in drugs along with other goals including the establishment of an effective drug procurement system, developing an efficient drug distribution system, the harmonization of drug legislation within the ECOWAS subregion, and a commitment to the rational use of medicines at all levels of health care.

To attain the aim of an increased share for locally produced medicines, some incentives have been introduced:

- Import prohibition of 18 essential medicines in which local manufacturers have adequate capacity to meet domestic demand (see Table 23)
- A tariff structure designed to discourage the import of those essential medicines which are manufactured locally (see chapter 4.5)
- Realistic measures to boost research and development of local sources of pharmaceutical raw materials, including active pharmaceutical ingredients and excipients

In 2005, a revised National Drug Policy was unveiled, designed to cater to changing circumstances in the sector. The revised NDP aims to provide the Nigerian population with adequate supplies of medicines that are effective, affordable, safe and of good quality, ensuring the rational use of such medicines and promoting increased local production of essential medicines.

The policy provides guidelines for the distribution of health products to both public and private health facilities. It also lays down measures to improve the distribution of medicines and medical supplies in the country. These include ensuring that the supply, sale and distribution of medicines is under the control of pharmacists. The measures also clearly define the respective roles of manufacturing, wholesaling and retailing within the medicines distribution chain. They are summarized in Box 5.

Box 5: Measures Designed to Promote Rational Drug Distribution in Nigeria

- Drug distribution, supply, sale and dispensing shall be under the control and supervision of pharmacists at all times
- Government shall ensure that drug manufacturing, wholesaling and retailing activities are registered as distinct enterprises
- The channel for private sector drug distribution shall flow from manufacturers or importers to wholesalers and retailers
- Government shall ensure that drug supplies to public health facilities are based on expressed need and shall generally be from the Central Medical Stores
- Government shall ensure that all medicines purchased or donated to governments at all levels are chanelled through the Central Medical Stores

- Government shall establish inventory control systems including computerisation in all hospital pharmacies and clinics to achieve effective inventory control which shall be linked to a central computerised inventory control system at the Central Medical Stores
- Adequate security shall be provided for storage areas and, in particular, for narcotic drugs
- Drugs distributed in the country shall, as a minimum, be labelled in English
- Government shall create incentives for pharmacists to establish practices in rural areas in order to promote rational drug distribution and use in such disadvantaged locations

4.5. Import policy on pharmaceuticals

Nigeria has banned the import of pharmaceutical products through all land borders with the aim of eliminating the inflow of substandard and counterfeit products. Pharmaceutical products can only be imported through the approved ports/channels listed in Table 22.

Table 22: Approved Ports for Entry of Imported Medicines

SEA PORTS		*AIR PORTS*	
1.	Apapa Area I Sea Port, Lagos	1.	Murtala Mohammed International Airport, Lagos
2.	Calabar Sea Port, Calabar	2.	Mallam Aminu Kano International Airport, Kano
3.	Port Harcourt I Sea Port, Port Harcourt	3.	Port Harcourt International Airport, Port Harcourt
		4.	Nnamdi Azikiwe International Airport, Abuja

The FMoH, in collaboration with PMG-MAN, assessed local capacity and capacity utilization for the production of some essential medicines and, as a result of this exercise, in April 2005 the import of 18 essential medicines was banned (see Table 23) in order to encourage local production. Interviews carried out with the Department of Food and Drug Services indicate that the FMoH is satisfied with the quality, quantity and cost of the essential medicines now produced inside Nigeria and substituting those on the banned list.

Table 23: List of Pharmaceuticals prohibited for Import into Nigeria, 2005

Number	*Products*	*Formulations*
1	Paracetamol	Tablets and Syrups
2	Co-trimoxazole	Tablets and Syrups
3	Metronidazole	Tablets and Syrups
4	Chloroquine	Tablets and Syrups
5	Haematinic Formulations	Tablets and Syrups
6	Ferrous Sulphate and Ferrous Gluconate	Tablets
7	Folic Acid	Tablets
8	Clotrimazole	Cream

Number	*Products*	*Formulations*
9	Ampicillin/Cloxacillin Combination	Capsules
10	Vitamin B Complex	Tablets (except modified release formulations)
11	Multivitamin	Tablets, Capsules and Syrups (except special formulations)
12	Aspirin	Tablets (except modified release formulations and soluble aspirin)
13	Magnesium Trisilicate	Tablets and Suspensions
14	Piperazine	Tablets and Syrups
15	Levamisole	Tablets and Syrups
16	Penicillin/Gentamycin	Ointments
17	Pyrantel Pamoate	Tablets and Syrups
18	Dextrose, Normal Saline	Intravenous Fluids

Source: Federal Ministry of Health, Abuja, 2010.

In 2006, the World Health Organization, in collaboration with FMoH, undertook a survey of medicine prices in Nigeria. Table 24 contains information derived from the WHO report on the survey and shows the comparison of the cost of some of the banned products with international reference prices. The survey showed that Paracetamol, Metronidazole and Ferrous Sulfate tablets were procured below the international reference prices. On the other hand, Cotrimoxazole tablets and syrups were marginally more expensive than international reference prices. It would be advisable to undertake such surveys regularly, including quality control analysis.

Table 24: Comparison of the Procurement Costs of Banned Medicines with International Reference Prices

Some Products Banned for Import	*Comments*	*Ratio of Local Price to International Price*
Paracetamol tablets and syrups		0.9
Cotrimoxazole tablets and syrups	Antibiotic agent	1.5 (tabs) 1.4 (susp.)
Metronidazole tablets and syrups	Antiparasitic agent	0.3 (tabs) 1.0 (syrups)
Chloroquine tablets and syrups	Malaria drug	-
[i] Ferrous sulphate and ferrous gluconate tablets [ii]Folic acid	Important maternal and child health (MCH) preventive drugs	0.2 -

Source: WHO Survey of Medicine Prices in Nigeria, 2006

The National Agency for Food and Drug Administration and Control (NAFDAC), in collaboration with Customs, is responsible for enforcing the policy on the import of banned medicines. Table 25 contains the list of additional health products which were scheduled to be added to the prohibition list in late 2010.

Table 25: List of Additional Health Products for Import Prohibition

Product Name	*Pharmaceutical Form*
Ampicillin	Capsules, Powder
Amoxicillin	Capsules, Powder
Chlorphenamine	Tablets, Syrup
Ascorbic acid	Tablets, Syrup
Tetracycline	Capsules 250mg
Ibuprofen	Tablets, Syrup
Dextrose 5%, 10%,	
Dextrose 5% + 0.9% NaCl	
Dextrose 5% + 4.3% NaCl and 0.9% NaCl	

Current import duties are perceived as positive by PMG-MAN, such as 0 per cent on active pharmaceutical ingredients (APIs) for ARVs/ACTs, 5 per cent for other raw materials and 20 per cent on finished imported products. Packaging material is available on the local market with very few exceptions (e.g. aluminium).

The tariff structure within the framework of the ECOWAS Common External Tariff (CET) came into effect in Nigeria in 2005. It was designed to discourage imports and stimulate local pharmaceutical production with provision made for tariff free import of industrial equipment and low tariff rates for the import of raw materials such as APIs and higher rates for the import of finished products. The key elements of the ECOWAS CET for inputs and finished pharmaceutical products are shown in Table 26 below.

Table 26: ECOWAS Tariff Structure for Imports of Pharmaceutical-related Items

	Items	*Tariff*
1	Essential medicines, industrial machinery and equipment	0%
2	Raw materials and other capital goods	5%
3	Intermediates	10%
4	Finished goods	20%
5	Finished products with adequate local production capacity	50%

A study conducted in 2009 (Botwe and Okelola, 2009) in the ECOWAS region detailed the tariffs in selected ECOWAS countries on imported medicines and medical devices from countries outside the ECOWAS subregion (Table 27).

Table 27: Tariffs on Medicines and Medical Devices in ECOWAS

	Country	*Tariff on Medicines*	*Tariff on Medical Devices*	*Remarks*
1	Cape Verde	0%	0%	Lusophone
2	Cote d'Ivoire	2.5%	26.5%	Francophone
3	Gambia	17.05%	17.05%	Anglophone
4	Ghana	17.0%	17.05% and 37.05%	Anglophone
5	Guinea Conakry	2.75%	27.01%	Francophone
6	Liberia	12.0%	12-14% and 50%	Anglophone

	Country	*Tariff on Medicines*	*Tariff on Medical Devices*	*Remarks*
7	Nigeria	26.5%	41.5%	Anglophone
8	Sierra Leone	30.0%	30.0%	Anglophone

It is encouraging for local manufacturers that finished imported medicines and medical devices attract relatively higher tariffs than APIs. Yet although, in the case of some medicines, the tariffs offer a degree of protection to local manufacturers, they still further increase costs and can make medicines more expensive than necessary for those sections of the population that desperately need these medicines.

4.6 Specific support polices

The 2002 Summit of African Heads of State in Nigeria published the Abuja Declaration and Framework for Action for the Fight against HIV/AIDS, TB and other related infections. This states that all tariff and economic barriers to accessing resources for the fight against AIDS should be removed and called for additional resources to be made available with a target of mobilizing funds equivalent to 15 per cent of national annual budgets for the health sector. Tax exemptions should also be applied to reduce the price of medicines and efforts made to develop the potential for producing effective and safe traditional medicines.

The government is committed to achieving national self sufficiency as defined by the NDP and to implement measures to curb the influx of counterfeit drugs. These measures have been designed by the FMoH, with some inputs from PMG-MAN, and are at various stages of implementation. They include the following:

- The strengthening of the pharmaceutical regulatory activities of NAFDAC
- Initiation by the Federal Ministry of Health of a bilateral agreement with Brazil for the local manufacture of ARVs. Under this agreement, two local manufacturers will benefit from skills and technology transfer from Brazil. Negotiations regarding the proposed bilateral agreement are still in progress.
- The promotion of research and development of new medicines targeting the treatment of malaria and HIV/AIDS based on indigenous medical knowledge and biodiversity
- Exploring the possibility of development and local manufacture of pharmaceutical grade raw materials
- Articulating an acceptable agreement involving all stakeholders which will further promote access to capital at reasonable interest rates (i.e. below 10 per cent). Such a process will involve the Governor of the Central Bank of Nigeria and the Managing Directors/Chief Executive Officers of commercial banks in the country.
- The ban on imports of additional pharmaceutical products which can be manufactured locally (see Tables 23 and 25 above)

4.7 The legal framework

Nigeria has been a member of the World Trade Organization (WTO) since 1995 and is classified as a Developing (DC) (not as a Least Developed Country - LDC). It benefited from a transition period – until the start of 2006 – to implement the TRIPS (Trade-Related aspects of Intellectual Property Rights) agreement although the regulations have yet to be fully transposed. Whilst Nigeria does not enjoy the special status of LDCs within the TRIPS agreement, it can take advantage of all other TRIPS flexibilities, such as the definition of patentable subject matter, the scope of patentability criteria, and compulsory licensing.

In fact, the local manufacture of ARVs, ACTs and anti-TB medicines does not contravene the TRIPS Agreement since, in most cases, local firms enter into partnership with foreign companies and produce under their licences. Currently, there are three Nigerian institutions dealing with intellectual property issues:

- The National Office for Technology Acquisition and Promotion (NOTAP), which comes under the aegis of the Federal Ministry of Science and Technology, and is responsible for conducting searches on behalf of any Nigerian who intends to patent an innovation or discovery. NOTAP guides individuals throughout the processes at no cost to the client and encourages them to patent their scientific findings. The Office also bears the cost of the patents.

- The Nigerian Copyright Commission (NCC), which comes under the Federal Ministry of Justice. The NCC deals only with copyrights and is empowered by law to enforce compliance.

- The National Patent Registry (NPR), under the aegis of the Ministry of Commerce and Industry, is responsible for patenting innovations and discoveries.

In 2006, the Government decided to merge the three organizations into the Nigerian Intellectual Property Organization (NIPO). A law establishing NIPO is currently in preparation.

In reality, however, Nigeria's intellectual property regime is more or less non-existent and therefore does not offer any meaningful patent protection according to interview results. Patenting is not an important concern for Nigerian manufacturers. Moreover, Nigeria is not yet a member of the African Regional Intellectual Property Organization (ARIPO) but simply an observer.

5. THE INSTITUTIONAL ENVIRONMENT

5.1 Regulatory agencies

Table 28 shows the current list of regulatory agencies of relevance to the pharmaceutical industry, as well as their mandates.

Table 28: Regulatory Bodies and their Mandates

	Regulatory body	*Mandate*
1	Corporate Affairs Commission (CAC)	Company registration
2	Federal Ministry of Commerce	Brand name registration and trademark approval
3	Nigerian Export Promotion Council (NEPC)	Export of regulated products
4	National Health Insurance Scheme (NHIS)	Registration and regulation of Health Maintenance Organizations (HMOs)
5	Pharmacists' Council of Nigeria (PCN)	Inspection and registration of pharmaceutical retail, wholesale and manufacturing premises
		Registration of pharmacists
		Regulation of the practice of pharmacy
		Inspection of manufacturing premises
6	National Agency for Food and Drug Administration and Control (NAFDAC)	Evaluation and registration of pharmaceutical products
		Post-market surveillance and risk analysis of registered products
		Control of product import and export
		Regulation of product promotion and public education
9	National Office for Technology Acquisition and Protection (NOTAP)	Regulation of technology acquisition and protection, including Intellectual Property Rights (IPR) issues, patents, benefit sharing, etc.

Frost & Sullivan, 2010

5.2 Regulatory control

The pharmaceutical industry in Nigeria is regulated essentially by two agencies, both of which come under the aegis of the Federal Ministry of Health. The Pharmacists' Council of Nigeria (PCN) regulates the practice of pharmacy and training of pharmacists, including the development of basic pharmacy curricula for degree programmes and mandatory continuing education programmes. The PCN also regulates all premises where pharmacists practice their profession, including manufacturing facilities, retail outlets, and drug warehouses. Thus, PCN inspects the premises to ensure compliance with GMP and approves the premises for pharmaceutical manufacturing.

The National Agency for Food and Drug Administration and Control (NAFDAC) regu-

lates all drug products and substances, chemicals, bottled water and packaged food. As NAFDAC also inspects the manufacturing premises to ensure that the facilities are satisfactory for production of the specific products, there is a need for the harmonization of Good Manufacturing Practice (GMP) inspections of manufacturing facilities as well as of human resource development planning by both PCN and NAFDAC.

In 2006, the West African Drug Regulatory Authorities Network (WADRAN) was established with the broad objective of harmonising food and drug regulations within the ECOWAS subregion. WADRAN headquarters are currently based at NAFDAC in Abuja.

5.2.1 National Agency for Food and Drug Administration and Control (NAFDAC)

The National Agency for Food and Drug Administration and Control (NAFDAC) was established by Decree 15 of 1993 and replaced the Department of Food and Drug Administration and Control (FDAC) within the Federal Ministry of Health. The agency is responsible for the regulation and control of pharmaceuticals in Nigeria. Its tardy establishment meant that between 1974, when the first food and drug decree was enacted, and 1994, when NAFDAC was established, no fake drug manufacturer or importer was ever prosecuted for endangering the lives of people. For example, there was public outrage when no culprits were indicted over the death of over 150 children who died in 1989 as a result of a formulation error in a drug.

NAFDAC has the responsibility "to protect public health by promoting wholesomeness, quality, safety and efficacy of processed food, medicines, cosmetics, medical devices, chemicals and pre-packaged water through an effective quality assurance system and public enlightenment in addition to inspectorate and enforcement activities as part of the nation's efforts to emphasise prevention of illnesses in all residents in Nigeria". The agency also has the task of formulating regulations and compiling standard specifications for compliance by manufacturers, importers and exporters of regulated products.

New directorates were created for Administration & Finance; Planning, Research & Statistics; Narcotics & Controlled Substances; Regulations & Registration Inspectorate; Laboratory Services; Enforcement; and Ports Inspection.

New inspectorate offices were opened in all the nation's 36 states, as well as in the Federal Capital, Abuja, and three special inspectorate offices, six zonal offices and three narcotic offices were also established. Laws that the new management considered out of step with global trends in the war against illicit drugs were also reviewed and sent to the National Assembly.

The Agency has focused on enforcement activities, which were identified as the weakest link in the chain of NAFDAC's regulatory responsibilities. The activities of the Ports Inspection and Enforcement directorates were strengthened and surveillance and establishment inspection activities intensified. These measures have shown remarkable results, with a very large increase in seizures and destruction of fake drugs. As of 2010, the agency had carried out a total of 60 destruction exercises of drugs and substances valued at over 4 billion Naira (US$ 28 million) and had placed some 3,760 tonnes of regulated products on "hold". In the Port Harcourt zone alone, NAFDAC has put on hold 229 containers of regulated products.

These successes are in large measure attributable to three new policies introduced by the Federal Government:

- The outright ban on the importation of drugs and other regulated products through land borders
- The designation of Calabar and Lagos (Apapa) sea ports, Murtala Muhammed and Aminu Kano international airports as exclusive ports of entry for the importation of drugs and pharmaceutical raw materials; and
- The release of shipping and cargo manifests by the Nigerian Ports Authority, shipping lines and airlines to NAFDAC inspectors.

Currently, all factories must be GMP certified by NAFDAC. Before any organization (public or private) is allowed to import drugs into Nigeria, NAFDAC must also inspect factories anywhere in the world before it registers or renews the registration of their products. For example, NAFDAC has appointed consultants in India who certify all drugs before they leave India for Nigeria. The Agency also now requires compulsory pre-shipment information from all importers before the arrival of their products.

In a wider context, NAFDAC has engaged the public proactively in the war against counterfeit drugs by regularly publishing the list of genuine products and their fake versions so that the public can make informed choices in the market place. The agency works closely with the police and the Federal Ministry of Justice to enforce its regulations and has had some success in advocacy on various aspects of substandard products. A national pharmacovigilance unit has been established, with zonal offices located at university teaching hospitals to collate information on all adverse reactions to drugs and subsequently to take appropriate enforcement action.

In 2006, in collaboration with WHO and funded by the UK's Department for International Development (DFID), NAFDAC conducted a study on its regulatory, surveillance and quality assurance resources. As a follow up action, through the Partnership for Transforming Health Systems II (PATHS II), DFID is supporting the NAFDAC Laboratory at Yaba, Lagos with modern analytical and quality control facilities for WHO certification for drug analysis (PATHS II, 2010).

Undoubtedly, the last decade in the pharmaceutical sector in Nigeria has been exciting, especially with the return to democratic governance and the political will of the Government to support the enforcement of pharmacy laws by the Pharmacists Council of Nigeria and NAFDAC. A very important development is that the level of counterfeiting of medicines was reduced from 40 per cent to 17 per cent in 2006 and was estimated to be less than 10 per cent in 2009 (NAFDAC, 2010). Table 29 shows estimates of the market share of counterfeit and substandard drugs in ECOWAS member countries.

Table 29: Estimates of the Market Share of Counterfeit and Substandard Drugs in ECOWAS Member Countries

Country	*Percentage Share*
Benin	30%
Burkina Faso	10%
Cote d'Ivoire	30%
Ghana	15%
Guinea	60%
Liberia	15%
Mali	15%
Niger	30%
Nigeria	17%
Senegal	12%
Sierra Leone	30%
Togo	25%

Source: Okelola, 2009.

In 2009, NAFDAC issued regulations on Nigerian Good Manufacturing Practice (NGMP). These are available on the NAFDAC website (www.nafdac.gov.ng). The agency has also organized training workshops on NGMP regulations for its pharmaceutical inspectors to strengthen capacity in standard inspection.

5.2.2 Regulatory requirements for local drug manufacturing

A pharmaceutical manufacturing company intending to manufacture pharmaceuticals in Nigeria should apply for a pre-production inspection by NAFDAC and should have at least one registered pharmacist on its Board of Directors. It must also appoint a superintendent pharmacist who is duly registered with the Pharmacists Council of Nigeria (PCN). In addition, the pharmaceutical manufacturing premises should be registered with PCN. Some of the necessary documentation for this registration is listed in Box 6 below.

Box 6: Documentary Requirements for the Registration of Pharmaceutical Premises

- List of qualified staff, their qualifications and status
- Organizational chart
- Factory layout chart
- Production flow chart
- Details of standard operational procedures
- List of products to be manufactured
- List of equipment for production and quality control
- List and sources of suppliers of raw and packaging materials
- Water source and treatment facilities
- Water analysis report (raw and treated water)
- Disposal of poison records

5.2.3 Product registration

Pharmaceutical products are required by law to be registered before marketing in Nigeria, as in other countries. This applies to both locally manufactured and imported products. The major steps involved include:

- Submission of a letter of application stating the name of the manufacturer; generic/common name and brand name of the product; product strength and indications
- Obtaining an application form upon payment of the application fee
- Submission of five hard-covered copies of the application dossier to NAFDAC, including a comprehensive certificate of analysis; certificate of incorporation of the applicant; evidence of trademark and brand name approval from the Ministry of Commerce; three vetting samples; current premises licence; annual licence for the superintendent pharmacist
- Payment of a registration fee, renewable every five years (700,000 Naira equivalent to US$ 4,605)
- Request for permission to advertise the product

Foreign manufacturers must be represented by local agents with duly registered premises and applications must be accompanied by evidence that a Power of Attorney has been granted to the local agent. A proposal for reciprocal registration of locally manufactured products within regional blocs by the African Union has not yet been implemented.

5.2.4 Pharmaceutical research bodies and training facilities[2]

Research into medicines and related supplies, including clinical trials, is regulated by NAFDAC. The country has a total of 66 established research parastatals with federal mandates in different federal ministries. Of these, five are of particular relevance to the local manufacturing of pharmaceuticals, especially antimalarials, ARVs and tuberculosis medicines, namely:

- The National Institute for Pharmaceutical Research and Development (NIPRD) in Abuja, which comes under the aegis of the FMoH. NIPRD is responsible for research into medicinal plants, herbs and drug development and formulary.
- The Nigerian Institute of Medical Research (NIMR) in Lagos, also under the FMoH, is mandated to conduct medical research into communicable diseases like malaria, human parasites and nutritional defect problems, genetic and non-communicable diseases and other public health related areas of interest.
- The National Office for Technology Acquisition and Promotion (NOTAP) in Abuja, which comes under the aegis of the Federal Ministry of Science and Technology, has a mandate to encourage a more effective process for the identification and selection of foreign technology, as well as to vet, register and monitor contract agreements for the acquisition of foreign technologies by Nigerians.

[2] This section of the report is reproduced from the Pharmaceutical Sector Profile of Nigeria published by UNIDO in January 2008.

- The Raw Materials Research and Development Council (RMRDC) in Abuja comes under the aegis of the Federal Ministry of Science and Technology and has a mandate to promote, support and expedite industrial development and self-reliance through the optimal utilization of local raw materials as inputs for the nations' industries.

- The Nigerian Natural Medicine Development Agency (NNMDA) in Lagos is responsible for initiation of policy and improving knowledge on the practice and potential of natural medicine with a view to fully developing and integrating it into the national health care delivery system. NNMDA comes under the aegis of the Federal Ministry of Science and Technology.

There are a further 63 scientific bodies organised under the Nigerian Community of Young Scientists (NICOYS) and located in different states across the country. These institutions are involved in several research activities and represent various scientific interests.

The training of pharmacists in Nigeria is regulated by the federal Pharmacists' Council of Nigeria, which accredits pharmacy training schools. Nigeria has a total of nine universities with pharmacy training schools at both undergraduate and postgraduate levels, including doctoral studies (see Table 30). These universities have produced a total of over 12,000 pharmacists, including those practising locally in Nigeria and those outside the country, the majority of whom are in the United Kingdom and the United States of America.

In addition to training pharmacists, universities contribute to the local manufacturing of generic medicines through collaboration with local manufacturers in research and development. The University of Lagos' School of Pharmacy, in particular, is collaborating with a number of manufacturers in the areas of quality control and stability studies.

Table 30: Pharmacy Training Institutions

1. Ahmadu Bello University Faculty of Pharmaceutical Sciences Zaria, Kaduna State	2. Obafemi Awolowo University Faculty of Pharmacy Ile-Ife, Oyo State	3. University of Benin Faculty of Pharmacy P.M.B. 1154 Benin City,Bendel State
4. University of Ibadan Faculty of Pharmacy Ibadan, Oyo State	5. University of Jos Faculty of Pharmacy Makurdi Campus Jos, Plateau State	6. University of Lagos School of Pharmacy College of Medicine P.M.B. 12003 Idi-Araba, Surulere Lagos State
7. University of Nigeria Nsukka Faculty of Pharmaceutical Sciences Nsukka, Anambra State	8. Olabisi Onabanjo University Faculty of Pharmacy Sagamu, Ogun State	9. University of Uyo Faculty of Pharmacy Uyo, Akwa-Ibom State
10. Faculty of Pharmacy Niger-Delta University Yenogoa, Bayelsa State	11. Faculty of Pharmacy Madonna University Elele, Rivers State	12. Faculty of Pharmacy Nnamdi Azikwe University Agulo, Anambra State
13. Faculty of Pharmacy University of Maiduguri Borno State		

These institutions are crucial for the training and continuing professional education of pharmacists, who are the core professionals in the production of drugs.

5.3 Professional associations

5.3.1 The Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN)

PMG-MAN is the umbrella organization for drug manufacturers in Nigeria and has over 100 local pharmaceutical companies as members although not all indigenous drug manufacturers belong to the Group. In order to qualify as a member, a company must have and utilize manufacturing facilities for the production of drugs and medicines from local and imported raw materials. It must be a member of the Manufacturers Association of Nigeria (MAN) and be duly registered for drug manufacture by the PCN and NAFDAC. The company must be seen to uphold the principles of Good Manufacturing Practice (GMP).

The objectives of PMG-MAN include:

- Promoting the manufacture of high quality finished medical products and raw materials in accordance with Good Manufacturing Practice (GMP)
- Improving the standards of pharmaceutical manufacturing in Nigeria
- Creating a forum for interaction and understanding between PMG-MAN and organizations within the same field
- Promoting and influencing drug policy with regard to industrial, labour, social, legal training and technical matters, etc.
- Developing and promoting the contribution of drug manufacture to the national economy through representations to all relevant government bodies

The Group's current activities include:

- Setting up a pharmaceutical information data base on drug manufacturing in Nigeria, including regularly updated profiles of individual companies; professional advocacy - PMG-MAN contributes to government policy formulation and implementation and supports public sector activities by, for example, serving on various Government committees where policies, regulations and quality of medicines, as well as access to medicines, are discussed
- organising public awareness campaigns

5.3.2 The West African Pharmaceutical Manufacturers Association (WAPMA)

The West African Pharmaceutical Manufacturers Association (WAPMA) was launched in Ghana in October 2005. Its objective is to promote pharmaceutical business, research collaboration and to serve as a credible body for interaction with ECOWAS and international development partners. In particular, it aims to:

- Promote the manufacture, marketing and distribution of high quality pharmaceuticals in accordance with GMP within the West African subregion
- Provide an information network and a system of cooperative assistance with pharmaceutical manufacturing and marketing companies and associations at the national, regional and international levels
- Represent the common interests of its members at the regional and continental levels, as well as to promote measures aimed at ensuring access to affordable medicines for patients in West Africa. This would be achieved by contributing to and influencing drug policies and regulations and encouraging harmonization within the subregion
- Inform its members of trends, developments and implications of any scientific, legal and technical issues impacting the pharmaceutical industry. A robust database of relevant publications and such information within the subregion and industry will be maintained
- Promote the development of raw materials, excipients and other inputs into pharmaceuticals, especially from herbal and mineral sources within the subregion
- Promote relations with other regions of Africa and the rest of the world on pharmaceutical matters
- Provide scientific, regulatory and legal expertise at the request of national, regional and international bodies
- Promote the development of pharmaceutical technology, research and manpower within the subregion and facilitate appropriate technology transfer
- Advise and facilitate tariffs, taxes and other fiscal policies to promote free trade within the subregion
- Cooperate with the Economic Community of West African States ECOWAS, the African Union and other multilateral bodies in health and trade matters

6. ENHANCING LOCAL PHARMACEUTICAL PRODUCTION CAPABILITIES: CHALLENGES AND PROSPECTS

6.1 Policy, legal and regulatory issues

Although the National Health Act is not yet promulgated into law, the revised National Health Policy was developed and approved in 2004 with key components covering the registration, manufacture, sale, importation and dispensing of pharmaceuticals. A strategic thrust in the revised policy is the promotion of local drug production through incentives such as the banning of products which can be manufactured in sufficient quantities to meet national demand; tariff restructuring to favour local drug production, etc. As a result of these policy initiatives, the capacity utilization of installed facilities increased from about 15 per cent in 2000 to 40 per cent in 2008. The pharmaceutical industry is currently vibrant and has experienced steady growth. For example, at least six companies are currently upgrading their facilities or building new facilities in order to satisfy the WHO prequalification and certification requirements.

6.2 Intervention fund

The intervention fund launched in July 2010 by the Government of Nigeria specifically for the power and manufacturing sectors is another positive development. The relatively low lending rate of 7 per cent, compared with the prevailing bank interest rate of 21 per cent, will enable pharmaceutical companies to draw on this fund to upgrade their facilities. Since the cost of utilities in the manufacturing sector is high, granting the power sector access to the intervention fund is another positive factor for the pharmaceutical manufacturing industry.

6.3 Research and development of medicines

The promotion of pharmaceutical research and development is another crucial health intervention. In a landmark innovation, the National Institute for Pharmaceutical Research and Development, with Government help, initiated and completed the research and development of a new phytomedicine (Niprisan/Nicosan) for the management of sickle cell anaemia. The product has been granted orphan drug status by both the United States Food and Drug Administration and the European Medicine Evaluation Agency. The fact that Niprisan/Nicosan is the only therapy which will be accessible to over 10 million sickle cell anaemia patients in sub-Saharan Africa will give a boost to the local pharmaceutical industry and NIPRD is now developing other phytomedicines for the management of prevailing priority diseases.

6.4 The market for illicit and counterfeit medicines

Corruption and lack of access to quality affordable essential medicines by the majority of the Nigerian population have contributed to the illegal trade in substandard and fake medicines in Nigeria. This problem poses a real challenge to manufacturers of genuine medicines. One step taken by most local drug manufacturers in order to combat the problem of fake and substandard medicines has been to develop tamper-proof containers although this increases the production cost and is passed onto the consumer. NAFDAC is also taking additional measures to reduce the incidence of fake and substandard medicines. Further strengthening the regulatory capacity to reduce the volume of counterfeit medicines and to supervise existing companies is a key factor in the successful development of the pharmaceutical sector.

6.5 Business opportunities in the ECOWAS subregion

The pharmaceutical industry in West Africa has enormous potential and opportunities for the expanded local production and supply of essential medicines. A conservative estimate of the population of ECOWAS is 280 million with a market size of around US$ 3.5 billion for health products. Moreover, Nigeria currently produces around 60 per cent of medicines produced in the subregion.

In view of the level of installed capacity for local drug manufacturing, its human expertise and experience, Nigeria will continue to play a critical role in local drug production in the subregion. The West African Drug Regulatory Agencies Network (WADRAN) is currently harmonizing the regulations of its members to boost trade within the ECOWAS subregion. Furthermore, the West African Pharmaceutical Manufacturers Association (WAPMA) is working to enhance confidence in the quality of medicines produced locally and subsequently to promote business in the subregion.

6.6 Capacity building

Training in pharmaceutical technical skills is of the utmost importance. The various practices used in the drug manufacturing sector are evolving and improving and new technologies are being introduced continuously to enhance quality compliance and manufacturing processes. Consequently, training workshops in current Good Manufacturing Practice (cGMP), validation and documentation are recommended to enhance their application and thus the improved performance of the sector.

6.7 Outlook and conclusions

The key objective of the pharmaceutical sector in Nigeria remains the attainment of self sufficiency in the supply of quality and affordable essential medicines to the population of more than 140 million in Nigeria and potentially to an additional 140 million in the ECOWAS subregion.

Government policy designed to promote the local production of essential medicines through a series of practical incentives is a major boost to the pharmaceutical industry in Nigeria.

Examples include the revised National Drug Policy (2004) aiming for local production of 70 per cent of essential medicines. The introduction of favourable tariffs for pharmaceutical raw materials and spare parts also underlines the support being given to local drug manufacturers. In 2005, the Government banned importation of 18 health products as a result of a survey which indicated that there was sufficient local manufacturing capacity in such products to meet local demand.

A robust and progressive pharmaceutical sector in Nigeria is foreseen in the coming decade. Stakeholders are collaborating in designing a mobile phone -based anti-counterfeiting system and technology verification techniques. Equally significant are forward strides in drug distribution through mega distribution companies such as MDS Pharma Logistics Limited and Worldwide Commercial Ventures Limited.

The following milestones, when reached, will have a very positive impact on the pharmaceutical business in Nigeria over the next 10 years:

- Improved distribution of medicines
- Advances in biotechnology
- The harmonization of medicine registration within ECOWAS
- WHO certification and prequalification of some Nigerian pharmaceutical manufacturers
- New phytomedicines developed by NIPRD and universities registered by NAFDAC and licensed to local pharmaceutical companies for commercial production and global marketing
- Development of pharmaceutical raw materials using indigenous basic raw materials

Annex 1. RECOMMENDATIONS FOR ACTION BY PMG-MAN

In the course of preparing this report, interactions with PMG-MAN indicated that the following are seen as priority areas where outside technical assistance is needed with the objective of supporting the expansion of the local pharmaceutical industry.

1.1 WHO certification and access to certified GMP consultants

There are more than 100 pharmaceutical manufacturers in Nigeria but none has so far met the requirements for certification by the World Health Organization (WHO). The following Nigerian companies have commenced the process to obtain WHO certification and prequalification:

- Swiss Pharma Nigeria Ltd. – has submitted an Expression of Interest to WHO
- Evans Medical Plc. - has rebuilt its existing factory to WHO standards
- May & Baker Nigeria Plc. - has a new factory compliant with WHO requirements under construction
- Afrab-Chem Limited – has a new factory compliant with WHO requirements under construction
- Daily-Need Industries Ltd. - has a new factory compliant with WHO requirements under construction

Level of Assistance so far received

The West African Health Organization (WAHO) has assisted two Nigerian companies (Evans Medical and May & Baker) by appointing a certified GMP consultant to advise them.

Proposed Intervention

To field certified GMP consultants who can provide manufacturers with state-of-the-art knowledge and understanding of internationally accepted manufacturing standards and practices which should lead to WHO certification and prequalification.

1.2 Training

Continuous training in the pharmaceutical sector is vital. The identified key areas include:

- GMP validation
- GMP and documentation
- The vital role of quality and compliance in business and life
- Risk management

Level of Assistance so far received

Two Nigerian pharmacists participated in UNIDO-sponsored Advanced Industrial Pharmacy training (2009/2010) in Kilimanjaro, Tanzania.

Proposed Intervention

A similar programme should be set up in Nigeria to benefit the whole West African subregion. The establishment of a pilot pharmaceutical production facility in Nigeria for training purposes to serve the whole ECOWAS subregion should be considered by international development partners. A possible site would be the National Institute for Pharmaceutical Research and Development (NIPRD) in Abuja.

1.3 Pilot phase of mobile phone-based anti-counterfeiting solutions

The level of counterfeit medicines circulating in Nigeria was estimated at about 17 per cent in 2005 but was considerably lower by 2009. Manufacturers' products are routinely faked and sold at lower prices than the genuine products. Consequently, local drug manufacturers are losing a significant share of the drug market in Nigeria to these illicit drug dealers. Stakeholders in the pharmaceutical sector reached a consensus that a cellular-based solution is realistic in order to confirm the quality of medicines. This entails placing ID numbers on all packs of medicines. The ID can be transmitted by telephone to a platform to confirm the integrity of the product. Designing a platform that is accessible to all Nigerians over the short–to-medium term is critical. Preferably, it should be cost-free to consumers and should allow the sharing of cellular devices, such as mobile phones and Personal Digital Assistants (PDAs) among users. Calling charges should not be allowed to deter use of this system in low income communities.

Level of assistance so far received

NAFDAC, PMG-MAN, and the Association of Nigerian Representatives of Overseas Pharmaceutical Manufacturers (NIROPHARM) are key stakeholders committed to launching a pilot project of this initiative using an agreed therapeutic class of products.

Proposed Intervention

The estimated cost of the proposed intervention is US$ 700,000 which would cover technical advice, research, data collection, technology testing and modelling, financial modelling and sensitivity analysis, simulations, the engagement of domain specialists in such areas as law, policy and social impact assessment, and the training required to enable stakeholders to engage with every aspect of each stage of the design and specification process.

1.4 Assistance to promote the local manufacture of pharmaceutical grade starch

Whilst local manufacturers of industrial grade starch exist in Nigeria, none produces pharmaceutical grade starch. However, the pharmaceutical sector requires over 100,000 tonnes of this type of starch annually, as well as allied products such as pre-gelatinised starch used as a binder in the industry and dextrose monohydrate marketed as glucose powder (nutraceuticals), which is a major ingredient in intravenous infusions.

Level of assistance so far received

The National Institute for Pharmaceutical Research and Development (NIPRD) has developed a successful pilot project for the production of pharmaceutical grade starch and potential investors in Nigeria and South Africa have been identified.

Proposed Intervention

Support is required for the preparation of a feasibility study and business plan and then for the start up of production and technical backstopping.

1.5 Mega Distribution Company

A major challenge to the pharmaceutical sector in Nigeria is the chaotic distribution system. The positive development is that there is a consensus on the part of all stakeholders that an efficient system is both desirable and achievable and the establishment of a mega distribution company is proposed.

Level of assistance so far received

A recent study carried out by the International Finance Corporation (IFC) of the World Bank Group recommended "establishing a consortium-based distribution system" which would make a real and substantive difference to the market in Nigeria. This would help to correct a major dysfunction and to pave the way for a strategic approach to "formalising the informal sector" in addition to being a good investment opportunity.

Proposed Intervention

The establishment of a mega pharmaceutical distribution company in line with the consortium-based system is proposed. The first steps would be the formulation of a feasibility study and a business plan. Assistance would also be needed with the start up of the company, technical support and information technology.

Annex 2. LIST OF THOSE INTERVIEWED

Name	*Designation*	*Telephone/e-mail*	*Organization*
Osunwa, Oliver Chinedu	Production Manager	08023299755 Kingolive2000@yahoo.com	Neimeth Pharma Plc.
Ademola Adeoti	CEO	08033029995 maadeoti@synergynggroup.com	Synergy Healthcare Limited
Otiko, A.F.S.	Superintendent Pharmacist		Vitabiotics Nig. Ltd.
Adefemi, Emmanuel Kola	Plant Operations Director/ Leader Logistics Management	08023770671	Neimeth Int. Pharmaceuticals Plc.
A.T. Mora	Registrar	08037038920	Pharmacists Council of Nigeria
Emma Ebere	MD/CEO	08034323415 emmaebere@hotmail.com	Archy Pharma Nigeria Ltd.
Ijimakin Ola Eboh	MD/CEO	08025186517 olasmail@gmail.com	Ecomed Pharma Ltd.
Eric Shall Iful	Deputy Director, Drugs and Cosmetics, EID, Abuja	08033863782	NAFDAC
Kunle Okelola	Executive Secretary	08033143499 Kunleok999@yahoo.com	PMG-MAN
J.E Babakandzhi Adagadzu	Director, Food & Drug Services	08032900765 jebadagazu@yahoo.com	FMoH
Steve Obami	Head of Marketing	obami@fidson.com	Fidson Healthcare Ltd.
Olugbenga Olayeye	Director, Sales & Marketing	mrolayeye@yahoo.com	Fidson Healthcare Ltd.
A.F.S. Otiko	Superintendent/ Pharmacist	08023770671 dayo.otiko@yahoo.com	Vitabiotics (Nigeria) Ltd.
Michael Ayebanjo Paul	Chairman/MD	mopsonpharma@yahoo.com	Mopson Pharmaceutical Industries Limited, Lagos
Vera N. Ogbeche	Deputy Director, Water Safety Management Programme, FMoH	08033200208 veraogbeche@yahoo.com	FMoH, Abuja

Name	***Designation***	***Telephone/e-mail***	***Organization***
J.A. Ugwu (Mrs)	Deputy Director, Pharmaceuticals	08039724655 Joyceugwu17@yahoo.com	FMoH, Abuja
John Idoko	Director General, NACA		NACA, Abuja
S.O.N. Akpa	MD/CEO	sona.rumon.org@gmail.com	SKG Pharma Plc., Lagos
Funmi Iayo B. Ige	Superintendent Pharmacist	08023186802 igefun@yahoo.com	SKG Pharma, Plc., Lagos
Amaka Okoye	MD/CEO	Juhel.3@gmail.com	Juhel Pharma., Enugu
Dinesh Kapoor	MD/CEO	08034004143 Dinesh.kapoor@ranbaxy.com	Ranbaxy Nig. Ltd., Lagos
Abbas Sambo	Deputy Managing Director	08037178441 abbas.sambo@swiphanigeria.com	Swiss Pharma Nig. Ltd, Lagos
Darwish Foundeh	MD/CEO	08033077566 darwishfoudeh@hotmail.com	Afrab Chem. Ltd., Lagos
Prince Femi Kobiowu	General Manager, TQM	08035057711 Kobifemi2003@yahoo.com	Mopson Pharmaceutical Industries Limited, Lagos
Femi Oyewole	Plant Manager/ Superintendent Pharmacist	08023844860 toludam@yahoo.co.uk	Gemini Pharmaceuticals Nig. Ltd.
Clayton W.L. Nwaka	Director, Finance	08032945047 cmwakaug@yahoo.com	Gemini Pharmaceuticals Nig. Ltd
Stella Denloye	Director, Laboratory Services	08023118986 Denloyestella@yahoo.com	NAFDAC
Monica Hemben Eimunjeze	Technical Assistant to DG	07065276680 meimunjeze@yahoo.com	NAFDAC
Thomas Omotayo Ilupeju	Pharmacist	08037033966 Iluta30@yahoo.com	Pharmacists Council of Nigeria (PCN)
G.O. Balogun (Mrs)	Director, Pharmaceutical Services	08034682432 Balogunoyikan@yahoo.com	Lagos State Ministry of Health, Lagos

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Annex 4. COMPANY PROFILES OF LOCAL MANUFACTURERS

Company Profile No. 1:	***Emzor Pharmaceutical Industries Ltd.***
Company Legal Status and ownership	Private Limited Company Started 23 years ago in 1987 100% Nigerian
Contact	Plot 3c Block A Aswan Market Road, Oshodi/Isolo Exp. Way P.O.Box 52053 Ikoyi, Lagos, Nigeria Phone +234 1 4523508, 7763863 Fax +234 1 4525884, 4525288 Email Info@emzorpharma.com Website www.emzorpharma.com
Company Size	Number of Employees: 525 as at 2009 Turnover (Million Naira) 2007 2008 2009
Product Range	Antimalarials, Antiretrovirals, Analgesics, Vitamins, Haematinics, Antihelmintic, Antitussives, Antacid, Antimicrobial Agents, Anti-Histamine

SWOT – Analysis

Strengths

- Established large distribution network
- Strong team (human capacity)
- Established brand

Weaknesses

- Limited funding for expansion and continuous improvement
- Lack of WHO prequalification

Opportunities

- Emerging market in Nigeria and ECOWAS
- Global initiatives on HIV/AIDS, TB and Malaria
- Economic and political environment

Threats

- Low purchasing power
- Counterfeits of own branded products
- Cheaper competing imported products

Company Profile No. 2:	***Evans Medical PLC*** *RC1161*
Company Legal Status and ownership	Public Limited Company 70% Nigerian and 30% foreign
Contact	Plot 6, Abimbola Way, Isolo PMB 1120, Apapa, Lagos, Nigeria Phone +234 7901401 – 8, 7919637 Fax +234 1 4529461, 4529469 Website www.evansmedical-ng.com

Company Size	Number of Employees:			339 as at 2009
	Turnover (Million Naira)			
	2007	2008	2009	
			4.5 billion Naira	
Product Range	ARVs, Antimalaria and Anti-TB drugs			

SWOT – Analysis

Strengths	***Weaknesses***
• Continuous staff training and development • Partnership with WHO certified companies like CIPLA Ltd. improved and better R&D • Established marketing and logistics system	• Limited funding for expansion and continuous improvement • Lack of WHO prequalification
Opportunities	***Threats***
• Emerging market in Nigeria and ECOWAS • Global initiatives on HIV/AIDS, TB and Malaria • Economic and political environment	• Low purchasing power • Counterfeits of own branded products • Cheaper competing imported products

Company Profile No. 3:	***May and Baker Nigeria PLC*** *RC 558*	
Company Legal Status and ownership	Public Limited Liability Company 100% Nigerian	
Contact	3/5 Sapara Street, Industrial Estate, Ikeja, Lagos and 1 May & Baker Ave, Ota, Ogun State	
	Phone	+234 12121290-91
	Fax	
	Email	info@may-baker.com
	Website	www.may-baker.com
Company Size	Number of Employees:	344 as at 2009
	Turnover (Million Naira)	
	2007 2008 2009	
	5.4 billion Naira	
Product Range	Antimalarials, Antibiotics, Antipyretics/Analgesics, Antihypertensives, Antidiarrhoeal, Antihistamines, Sulphonamides, Cough & Cold Preparations, Antidiabetics	

SWOT – Analysis

Strengths	***Weaknesses***
• Established and trustworthy company • Strong corporate image and brand identity • Distribution network • Good relationship with financial sector	• Few innovative products in portfolio • Few 'cash cows' • Poor product support • Large administrative workforce

Company Profile No. 4:	***Fidson Healthcare PLC*** *RC 267435*
Company Legal Status and ownership	Private Limited Company 100% Nigerian
Contact	Head Office: 268 Ikorodu Rd, P.O.Box 7210, Shomolu, Lagos Factory: Km 38, Abeokuta Expressway, Sango-Ota. Ogun State Phone +234 1 4933319, 4976171 Fax +234 1 4930841, 4960118 Email Info@fidson.com Website www.fidson.com
Company Size	Number of Employees: 294 as at 2008 Turnover (Million Naira) 2007 2008 2009 4.5 billion Naira
Product Range	Antiretrovirals, Antitubercular Drugs, Antimalarials, Antibacterials, Chondroprotective/Antiosteoarthritis, Analgesics/Anti-inflammatory, Antiulcers, Haematinics, Dermatologicals, Cough Syrups, Antidiabetes, Antihypertensives, Anticoagulants, Neuro-Psychiatry drugs, Obstetrics

SWOT – Analysis

Strengths

- Dynamic and focused staff
- Established and clear company vision
- On the job staff training through partnerships

Weaknesses

- Limited funds
- Lack of WHO prequalification

Opportunities

- Emerging market
- Improving investor confidence in Nigeria
- Global Initiatives on HIV/AIDS, TB and Malaria

Threats

- Lack of utilities (power and water)
- Security of life and property
- Cheap competing imports

Company Profile No. 5:	***Swiss Pharma Nigeria Ltd.*** *RC16806*
Company Legal Status and ownership	Private Limited Company 61% foreign (Swiss & British) and 39% Nigerian
Contact	5 Dopemu Road, Agege P.O.Box 463, Ikeja, Lagos, Nigeria Phone Fax 01 -4920543/4, 4923444, 4925767 Email swipha@swiphanigeria.com Website www.swiphanigeria.com
Company Size	Number of Employees: 350 as at 2009 Turnover (Million Naira) 2007 2008 2009 2.8 billion Naira

Product Range	Antimalarials, Antiretrovirals, TB D rugs

SWOT – Analysis

Strengths

- Established reputation for quality
- Established market structure
- Ability to expand and utilize the existing capacity in view of changing trends

Weaknesses

- Finance for expansion
- Lack of WHO prequalification

Opportunities

- Market (Export to ECOWAS countries)
- Global initiatives on ARVs, antimalarials and TB medicines procurements

Threats

- Counterfeits
- Cheap competing imports
- Staff attrition

Company Profile No. 6:	***Vitabiotics (Nigeria) Ltd.***
Company Legal Status and ownership	Private Limited Liability Company 60% foreign (British) and 40% Nigerian
Contact	35 Mobolaji Johnson Avenue, Oregun Industrial Estate P.O.Box 3020, Ikeja, Lagos, Nigeria Phone +234 1 4973717, 4973718 Fax +234 1 490852 Email Website www.vitabiotics.com
Company Size	Number of Employees: 259 as at 2008 Turnover (Million Naira) 2007 2008 2009 1.6 billion Naira
Product Range	25 different products including ARVs, anti TB (production was suspended because of low sales)

SWOT – Analysis

Strengths

- 30 years local manufacturing experience
- Capacity (human resources and machinery)
- Ability to expand and utilize the existing capacity

Weaknesses

- Retention of highly skilled personnel
- Lack of WHO prequalification

Opportunities

- Export to ECOWAS countries
- Development of new products in view of many global initiatives on ARVs, antimalarials and anti-TB medicines
- Existing but not utilized capacity

Threats

- Faking of company brands in Nigeria
- Poor utilities
- Competition from imported pharmaceuticals

Company Profile No. 7:	***Mopson Pharmaceutical Industries Ltd.***
Company Legal Status and ownership	Private Limited Liability Company 100% Nigerian
Contact	Mopson House 47, Osolo Way, Ajao Estate P.O. Box 5147, Oshodi, Lagos, Nigeria Phone +234 1 4523237, 4745548 Fax +234 1 4523237 Email mopsonpharma@yahoo.com Website
Company Size	Number of Employees: 202 as at 2008 Turnover (Million Naira) 2007 2008 2009 417.5 million Naira
Product Range	30 products including Anti-TB, ARVs, and Antimalarials

SWOT – Analysis

Strengths

- Dedicated and focused management and staff
- Continuous staff training
- Established marketing and logistics systems

Weaknesses

- Limited funding for expansion and continuous improvement
- Lack of WHO prequalification

Opportunities

- The continuous development of local production capacity
- Emerging market in Nigeria and ECOWAS
- Economic and political environment

Threats

- The cost of utilities (power, water)
- Cheaper competing imported products
- Poor infrastructure, especially roads

Company Profile No. 8:	***Ranbaxy Nigeria Ltd.***
Company Legal Status and ownership	Private Limited Liability Company 100% Nigerian
Contact	1st Floor Abimbola House 24 Abimbola Street , Ilasamaja, Isolo P.O.Box 4452, Ikeja, Lagos, Nigeria Phone +234 1 4526359, 4527094 Fax +234 1 4526371, 4527545 Email Dinesh.kapoor@.ranbaxy.com Website www.ranbaxy.com
Company Size	Number of Employees: 133 as at 2008 Turnover (Million Naira) 2007 2008 2009 3.5 billion Naira
Product Range	19 different products including 3 oral liquid ARV preparations

SWOT – Analysis

Strengths	***Weaknesses***
• Ranbaxy is a global multinational • Access to technology and technical support for a wide range of products • Established marketing and logistics systems- the company has been in Nigeria for the last 30 years	None indicated
Opportunities	***Threats***
• Emerging market in Nigeria and ECOWAS countries • Increasing range of products	• The cost of utilities and poor infrastructure • Counterfeits • Cheaper competing imported products

Company Profile No. 9:	***Ecomed Pharma Ltd.***
Company Legal Status and ownership	Private Limited Company 50% Nigerian and 50% foreign
Contact	Head Office: 215/219 Ikorodu Road, Obanikoro, Lagos, Nigeria Factory: Lynson Chemical Avenue, Km 38 Lagos Abeokuta Express-way, SangoOta, Ogun State, Nigeria Phone +234 8062318373, 8025186517 Fax Email Info@ecomedpharma.com Website www.ecomedpharma.com
Company Size	Number of Employees: 84 as at 2009 Turnover (Million Naira) 2007 2008 2009 293.7 million Naira 380 million Naira
Product Range	30 different products including 2 ACTs

SWOT – Analysis

Strengths	***Weaknesses***
• Established joint venture partnership with VC India • Strong brand identity • Established marketing and logistics system	• Lack of WHO prequalification • Limited funding for expansion and continuous improvement
Opportunities	***Threats***
• Emerging market in Nigeria and ECOWAS • Continuous development of local production capacity • Economic and political environment	• Cost and quality of utilities (power, water) • Poor infrastructure (especially roads) • Cheaper competing imported products

Company Profile No. 10:	***Nigerian–German Chemicals PLC***

Company Legal Status and ownership	100% Nigerian
Contact	Km 38 Abeokuta Expressway, Sango Ota, Ogun State Plot 144, Akran Avenue, Ikeja, Lagos State Phone +234 18971930 Fax Email enquirires@ngcplc.com Website www.ngcplc.com
Company Size	Number of Employees: 168 as at 2008 Turnover (Million Naira) 2007: 2.6 billion Naira; 2008: 2.77 billion Naira; 2009
Product Range	65 Products: ARVs, anti-TB, antimalaria

SWOT – Analysis

Strengths

- NGC is a global multinational
- Access to technology and technical support for a wide range of products
- Established marketing and logistics systems

Weaknesses

- Available funds for investment
- Ever changing policies of Government
- Old production facility

Opportunities

- Emerging market in Nigeria and ECOWAS countries
- Increasing range of products

Threats

- High cost of utilities and poor infrastructure
- Counterfeiting of products
- Cheaper imported products

Company Profile No. 11:	***ARCHY PHARMACEUTICALS LIMITED***
Company Legal Status and ownership	Private Limited Company 100% Nigerian
Contact	30 Winfunke Str. off International Sank Junction, Lagos Abeokuta Expressway, Ojokoro, Lagos Phone +234 1 7948705 Fax Email archypharma@yahoo.com Website www.archypharm.com
Company Size	Number of Employees: 120 as at 2009 Turnover (Million Naira) 2007 2008 2009
Product Range	ARVs, anti-TB, antimalaria

SWOT – Analysis

Strengths

- Established large distribution network
- Strong team (human capacity)
- Established brand

Weaknesses

- Limited funding for expansion and continuous improvement
- Lack of WHO prequalification

Opportunities

- Emerging market in Nigeria and ECOWAS
- Global Initiatives on HIV/AIDS, TB and Malaria
- Economic and political environment

Threats

- Low purchasing power
- Counterfeits of own branded products
- Cheaper competing imported products

Company Profile No. 12:	***SKG PHARMA LIMITED***
Company Legal Status and ownership	Private Limited Company 60% foreign (British) and 40% Nigerian
Contact	7/9 Sapara Street, off Oba Akran Avenue, Ikeja, Lagos State Phone +234 1 9504839 Fax Email rumoncare@yahoo.com Website
Company Size	Number of Employees: 227 as at 2008 Turnover (Million Naira) 2007 2008 2009 1.2 billion Naira
Product Range	60 products including ACTs

SWOT – Analysis

Strengths

- Established large distribution network
- Strong team (human capacity)
- Established brand

Weaknesses

- Limited funding for expansion and continuous improvement
- Lack of WHO prequalification

Opportunities

- Emerging market in Nigeria and ECOWAS
- Global Initiatives on HIV/AIDS, TB and Malaria
- Economic and political environment

Threats

- Low purchasing power
- Counterfeits of own branded products
- Cheaper competing imported products

Company Profile No. 13:	***AFRAB CHEM LIMITED***

Company Legal Status and ownership	Private Limited Company 90% foreign (Jordanian) and 10% Nigerian
Contact	22 Abimbola Street, Isolo Industrial Estate, Isolo, Lagos Phone +234 1 2700057, 4522571, 4522777 Fax Email info@afrab.com Website www.afrabchem.com
Company Size	Number of Employees: 178 as at 2008 Turnover (Million Naira) 2007 2008 2009 1.1 billion Naira
Product Range	40 Products

SWOT – Analysis

Strengths	***Weaknesses***
• Established large distribution network • Strong team (human capacity) • Established brand	• Limited funding for expansion and continuous improvement • Lack of WHO prequalification
Opportunities	***Threats***
• Emerging market in Nigeria and ECOWAS • Global Initiatives on HIV/AIDS, TB and Malaria • Economic and political environment	• Low purchasing power • Counterfeits of own branded products • Cheaper competing imported products

Company Profile No. 14:	***NEIMETH INTERNATIONAL PHARMACEUTICALS PLC***
Company Legal Status and ownership	Private Limited Company 100% Nigerian
Contact	Plot 16, Akani Doherty Layout, Oregun Industrial Estate, Ikeja, Lagos Head Office: 1 Henry Carr Street, PMB 21111, Ikeja, Lagos Phone +234 1 4742911, 7202356, 8990741/2 Fax +234 1 4525884, 4525288 Email Info@neimethplc.com Website www.neimethplc.com
Company Size	Number of Employees: 279 as at 2009 Turnover (Million Naira) 2007 2008 2009 1.75 billion Naira
Product Range	43 products that include veterinary, human and herbal medicines

SWOT – Analysis

Strengths	***Weaknesses***
• Established large distribution network • Strong team (human capacity) • Established brand	• Limited funding for expansion and continuous improvement • Lack of WHO prequalification
Opportunities	***Threats***

- Emerging market in Nigeria and ECOWAS
- Global Initiatives on HIV/AIDS, TB and Malaria
- Economic and political environment
- Low purchasing power
- Counterfeits of own branded products
- Cheaper competing imported products

Company Profile No. 15:	***Gemini Pharmaceuticals Nigeria Limited*** *RC 12547*
Company Legal Status and ownership	Private Limited Company
Contact	Plot 13, Block A, Industrial Estate, Amuwo-Odofin, Lagos Phone +234 4744974, 7901184 Fax Email info@geminipharmltd.com Website www.geminipharmltd.com
Company Size	Number of Employees: 135 as at 2009 Turnover (Million Naira) 2007 2008 2009 615 million Naira
Product Range	17 Products: Antibiotics, Antifungals, Scabicides, Antihypertensives, Analgesics

SWOT – Analysis

Strengths

- An offshoot of BAYER AG, Leverkusen with inherited products, formulation and technology
- Adequate personnel and technology capacity
- Products registered in Nigeria and Uganda by the national regulatory authorities
- Good understanding of the markets in Nigeria and Uganda

Weaknesses

- Inadequate operating funds
- Under-utilized installed capacity

Opportunities

- Large market in Nigeria, West Africa and Africa

Threats

- Parallel importation of Prescription only medicines (POM)
- Poor public energy (power) supply

Annex 5. QUESTIONNAIRE FOR COMPANIES INTERVIEWED

A. COMPANY PROFILE

Name of Company:

CAC Registration No: PCN Current Annual Licence No:

Physical location address:

Telephone(s)

Email Website

Contact person (s) Email : mobile:

(1) (1)

(2) (2)

(3) (3)

B. COMPANY OWNERSHIP STRUCTURE/INVESTMENT

(1) Ownership (1) Private % ___ Public% ___

(2) Total value ___ Local ownership % ___ Foreign ownership % ___

(3) Are you currently receiving any financial or technical assistance from Donors / International Agencies? Yes/No___

(4) Technology transfer Yes/No _____ If Yes state origin_____

C.MANAGEMENT STRUCTURE

(1) Please provide an organisational chart of key management personnel showing name, qualification(s) and positions

(2) Number of Staff Male Female

Total

Senior

Junior

D. CAPACITY UTILISATION

Formulation	***Human*** Installed	% Utilised			***Veterinary*** Installed	% Utilised			Expansion plans x2; x3, etc.
		2007	2008	2009		2007	2008	2009	
Tablets									
Capsules									
Dry syrups									
Syrups									
Suspensions									
Creams/ointments									
SVP/ LVP									
Sterile production (e.g. Water for injections, I.V. fluids, etc.)									
Bottled water & food products									
others									

E. TYPE OF MEDICINES MANUFACTURED

(1) ARVs	(2) ACTs	(3) Anti-TB	(4) Antibiotics
(5)	(6)	(7)	(8)
(9)	(10)	(11)	(12)
(13)	(14)	(15)	(16)
(17)	(18)	(19)	(20)
(21)	(22)	(23)	(24)
(25)	(26)	(27)	(28)

F. RESEARCH AND DEVELOPMENT

(1) Is there a research Unit?	Yes/No ___	
(2) Is there collaboration with Research Institutes/ Universities	Yes/No ___	
(3) Names of collaborating Institutions:		
(4) What is the research budget?	NGN _____	USD _____
(5) What kind(s) of research?	(a) Improve production technology	
	(b) Formulation studies	
	(c) Develop QC assay methods	
	(d) Herbal medicine R & D	
	(e) Others (specify) _____	
(6) What are your future plans for research?		

G. PRODUCTION INPUTS AND QUALITY

(1) Machines	Sourcing a. Imported b. Locally fabricated c. Locally purchased d. Others ----------	State the frequency of: a. Maintenance/Repairs _____ b. Spares and accessories _____ c. Replacement/upgrading _____
(2) Water	Source: a. Borehole b. Public supply c. Both a & b above	Give a brief description of your water treatment procedure: _____ _____
(3) Energy	Source: a. Generator b. Public c. Solar	
(4) Raw materials	Active a. Imported b. Locally sourced Non-active a. Imported b. Locally sourced	Are your raw material suppliers prequalified? a. Yes/No _____
(5) Production cycle	a. 24 hrs 7 days a week b. 8 hrs 7 days a week c. _____ d. _____	e. _____ f. _____ g. _____

(6) What particular challenges do you face regularly in the production process?

(7) How do you ensure that your packaging meets the right standards and is of the exact specifications?

(8) How do you ensure that your finished products are up to the standards set by regulatory bodies?

(9) Do your products require specialised storage conditions (e.g. Vaccines)?
a. How do you ensure that such conditions are maintained from production until consumption (or purchase)?_____

(10) What GMP certifications have you?
a. NAFDAC _____ b. WHO _____ c. Others (specify) _____

(11) Have you applied for WHO prequalification? Yes/No _____
If not, Why? _____

H. MARKETS, MARKETING & TAXATION

(1) Where are your markets?
a. Nigeria _____ b. West Africa _____ c. East Africa _____
d. Southern Africa _____ e. North Africa _____
f. Others (specify) _____

(2) Are some of your drugs targeted at:
a. Certain population (e.g. HIV/AIDS, TB, age group, etc)? If yes, please specify
_____
b. General population

(3) How are the medicines distributed?
a. In-house Department is responsible
b. Use of a third party or vendors
c. Others (specify)
_____

(4) Do you export your drugs? Yes/No _____
What percentage of your products do you export? _____
What challenges do you face in the exportation process? _____

(5) How do you inform prescribers and users of your products of their existence and availability?

(6) What challenges do you face in distributing your products?

(7) What factors contribute to an increase in product price?
a. Production/quality control cost
b. Infrastructural cost
c. Personnel cost
d. Registration cost
e. Others (specify)
_____

(8) Do price regulation and printing of retail prices on labels appeal to you? Yes/No _____
Why? Give reasons _____

(9) How do you rank the cost of your products?
a. High ____ Moderate ____ Low ____
b. Affordable ____ Unaffordable ____

(10) Does your company offer any form of discount on products? Yes/No _____
If yes, specify discount percentage _____%

(11) Is demand for all your products high or low? _____
Are you always able to keep up with demand? Yes/No _____

(12) What taxes do you pay as a company?
a. Importation/exportation
b. Federal
c. State
d. Local Governments
e. Advertisement
f. Others (specify)
_____

I. INTELLECTUAL PROPERTY

(1) Are you aware of the provisions of the 1995 Trade-Related aspects of Intellectual Property Rights (TRIPS) agreement, the 2001 Doha Declaration, and the 2003 agreement preceding the Cancun meeting?

a. Yes/No

b. Some aspects

(2) Do you possess a voluntary licence arising from Intellectual Property or TRIPS flexibilities? Yes/No _____

If yes, state product and patent holder (attach a list if required)

a. Product 1 _____ patent holder _____

b. Product 2 _____ patent holder _____

K. POLICY AND DRUG REGULATORY CONTROL

(1) What government policy or policies help to enhance your production and distribution processes? Give specific examples and details.

a. _____

b. _____

c. _____

d. _____

e. _____

(2) What government policy or policies hinder(s) or make(s) your production and distribution processes more difficult? Give specific examples and details.

a. _____

b. _____

c. _____

d. _____

e. _____

(3) What changes in government policy or policies would enhance production and distribution of your products?

_____

(4) Are your products registered with any regulatory bodies? Yes/No _____

Which ones? Specify _____

(5) Describe the registration experience?

a. Satisfactory

b. Not satisfactory

c. Needs improvement, specify areas; _____

(6) Does the registration process affect any of these processes?

a. Production

b. Importation

c. Exportation

d. Prices of finished products

e. Others, specify _____

L. TRAINING AND RE-TRAINING

How do you ensure that your staff are well trained and knowledgeable in their respective areas of speciality?

_____

M. GENERAL COMMENTS AND OTHERS SERVICES

What kind(s) of support in your opinion would make your production and distribution processes more efficient?

_____
_____
_____
_____
_____
_____

What other kinds of services do you render? Yes/No ___

To whom do you render such services?

_____
_____

General comments:

_____
_____
_____
_____
_____
_____

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Pharmaceutical Sector Profile: Nigeria

Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries

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